Pharmaceuticals and Condoms

An Additional Help Document for ADS Chapter 312

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The Bureau for Global Health's Office of HIV/AIDS/Supply Chain for Health Division (GH/OHA/SCH) has written this in an attempt to provide USAID's Implementing Partners (IPs), USAID technical and procurement staff, and others with helpful information on USAID-financed condoms, pharmaceuticals and medical supplies. We hope that you find it helpful, and we welcome your feedback.

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Part 1: ADS 312 Restricted Commodity Approval

1. ADS 312 sets out the requirements for approval of USAID-financed pharmaceuticals, condoms, and other restricted commodities. ADS 312 is not automatically applicable to USAID contracts and agreements.

2. ADS 312 applies when 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 USAID’s payment is based on the cost of specific pharmaceuticals or other goods and services.

3. ADS 312 does not apply where USAID payment is based, not upon specific costs, but on deliverables, results, achievement of milestones, or similar bases to achieve the purpose of the contract or agreement, *e.g.,* fixed-amount grants, loan guarantees or general or program contributions to public international organizations.

Part 2: Pharmaceuticals

I. Pharmaceuticals (other than Contraceptives)

1. **Contraceptives.** Please see Part 3 for approval of contraceptives.

2. **Veterinary Pharmaceuticals** are pharmaceuticals, not agricultural commodities.

3. **Laboratory Supplies**, such as medical gloves, syringes, laboratory reagents, tubes, and pipettes are not pharmaceuticals and do not require ADS 312 approval.

4. **ADS 310, 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 syringes, 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 extended the 2011 waiver which expired on September 30, 2016.

II. Responsibilities

1. The Bureau for Global Health's 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's Office of Population and Reproductive Health (GH/PRH) approves contraceptives.

2. The pharmacists in the Bureau for Humanitarian Assistance (BHA) have authority to approve pharmaceuticals for BHA programming under a delegation from OHA/SCH. For pharmaceuticals funded by BHA, please contact BHA.TPQ.Pharmacists@usaid.gov or review the BHA Emergency Application Guidelines and Pharmaceutical Guidance at https://www.usaid.gov/humanitarian-assistance/partner-with-us/bha-emergency-guidelines. BHA has its own approval procedures.

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

4. The technical staff in the Bureau for Global Health (GH) have been delegated the authority in ADS 312 authority to concur and advise on the quality of pharmaceuticals.

III. The OHA/SCH Approval Process

The purpose of the process is to determine if there is sufficient information 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.

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

The 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 procurement agent;

- Quality testing protocol (*e.g.,* 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

Different categories of pharmaceuticals have different requirements.

A. ADS 312 Approved Pharmaceuticals

OHA/SCH has approved the following pharmaceuticals under ADS 312 approval and they do not require further ADS 312 approval:

1. **Antiretrovirals (ARVs)**. ARVs approved by the U.S. Food and Drug Administration (FDA) and USAID. Please see **President's Emergency Plan for AIDS Relief (PEPFAR) Database.**

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**; and

    - **USAID List of Approved HIV Rapid Test Kits.**

3. **Pharmaceuticals under FDA Emergency Use Authorization.** Any pharmaceutical that is under FDA EUA for use in an emerging pandemic threat.

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., an approved wholesaler.[1]

Category 1: The U.S. Federal Drug Administration (FDA) and other National Drug Regulatory Authorities (NRAs) recognized internationally as Stringent Regulatory Authorities (SRAs). Please see Attachment A for a list of USAID-recognized countries with SRAs.

Category 2: Approved Wholesalers. See Attachment B for the list of approved wholesalers.

Category 3: UNICEF and WHO. Manufacturers approved by UNICEF and World Health Organization (WHO). 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.

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.

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] To ensure the 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.

1. We encourage you to contact OHA/SCH at **ads312approvals@usaid.gov** early in the process of procuring pharmaceuticals. We recommend obtaining ADS 312 approval of possible sources before asking for bids and only seeking bids from source(s) that have ADS 312 approval.

2. **Approval Template**. Please use the **Template for Restricted Commodity Approval for Pharmaceuticals**. Please email your template to **ads312approvals@usaid.gov**.

3. Be sure to include the following information:

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

4. **Additional information regarding quality**. For "other pharmaceuticals" you will 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.

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. It is the responsibility of the USAID technical team or IP to comply with section 606(c). 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. A sample letter to a contractor/recipient for advance approval of pharmaceuticals is in Attachment D.

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 may

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**.

Part 3: Male and Female Condoms

I. Responsibility

In October 2017, the Bureau for Global Health's Office of Population and Reproductive Health (GH/PRH) delegated OHA/SCH the responsibility for the management of male and female condoms and personal lubricant procurement (collectively "condoms") and related supply chain activities. GH/PRH continues to approve contraceptives. Funding for condoms remains divided among different USAID offices and sources but their procurement is managed by OHA/SCH.

II. ADS 312 Approval

OHA/SCH procures condoms for USAID projects under OHA/SCH-managed contracts. An IP must obtain prior written approval from OHA/SCH to procure condoms outside of OHA/SCH managed contracts. This **ADS 312** approval is required in addition to the nationality-source requirements in **ADS 310**.

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 the condom t 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 product.

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 (SRA), the United Nations International Children's Emergency Fund (UNICEF) or the World Health Organization (WHO);

- Source of the product (*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 the product; and
- Proposed use of the product (for example, basic research, field trials or clinical use).

III. OHA/SCH Contact

Please contact **ads312approvals@usaid.gov** if you are requesting approval to procure condoms under your agreement. Questions about condom procurement, quality assurance, or supply chain system strengthening or PEPFAR's core funded Condom Fund (Commodity Fund) can be directed to OHA/SCH at **ads312approvals@usaid.gov.**

Attachment A - List of Countries with USAID-Recognized SRAs

1. Australia
2. Austria
3. Belgium
4. Bulgaria
5. Canada
6. Cyprus
7. Czech Republic
8. Denmark
9. Estonia
10. European Union*
11. Finland
12. France
13. Germany
14. Greece
15. Hungary
16. Iceland
17. Ireland
18. Italy
19. Japan
20. Latvia
21. Liechtenstein
22. Lithuania
23. Luxembourg
24. Malta
25. Netherlands
26. Norway
27. Poland
28. Portugal
29. Romania
30. Slovakia
31. Slovenia
32. Spain
33. Sweden
34. Switzerland
35. United Kingdom
36. United States

*While the European Union is not a country, the European Medicines Agency applies the regulatory framework for pharmaceuticals across all the Member States of the European Union ('EU') and the European Economic Area ('EEA').

Attachment B - 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 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.

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

d. **Further information and the procedures for OHA/SCH approval can be** found under the **Technical Guidance section** of the Office of HIV/AIDS Web site.

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 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]

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