

Frequently Asked Questions (FAQs) on ADS 312 – Restricted Commodity Approval

Pharmaceuticals are defined by USAID to be restricted commodities. Prior to the financing of pharmaceuticals with USAID funds, CORs/AORs must obtain prior written approval attesting to the quality of such pharmaceuticals, as referenced in ADS312. This approval is in addition to the source–nationality requirements outlined in ADS310. As of February 2011, the Administrator approved a source–nationality waiver for all USAID–financed pharmaceuticals purchased from February 1, 2011 through December 31, 2016; therefore, an additional source–nationality waiver is not required.

GH/OHA/SCH is responsible for ADS312 approval of most pharmaceuticals, with the exception of contraceptives and malaria related commodities, which are the responsibility of GH/PRH/CSL and GH/HIDN/ID, respectively. (Specific contact information is provided at the end of this FAQ sheet.)

1. Which types of commodities already have ADS312 approval and do not require submission of a request for approval spreadsheet?

- a. Antiretrovirals (ARVs) on the PEFPAR and USAID Consolidated List of Approved ARVs
NOTE: This list includes FDA approved and FDA-tentatively approved ARVs. It does not include WHO prequalified ARVs.
- b. Rapid test kits on the USAID List of Approved HIV/AIDS Rapid Test Kits

2. What are USAID–approved sources for quality pharmaceuticals?

- a. Manufacturers approved by
 - i. a Stringent Regulatory Authority (ie. USFDA, EMA, Health Canada, Japanese Ministry of Health, Labor, and Welfare, and stringent regulatory authorities of member states admitted to the European Union prior to 1996)
 - iii. WHO Prequalification of Medicines Programme

3. What are other USAID approved sources for quality pharmaceuticals?

- a. Pharmaceuticals procured from UNICEF
- b. Pharmaceuticals procured from procurement agents approved by USAID*

*PLEASE NOTE: Pharmaceuticals must be procured directly from an approved procurement agent. The aforementioned list is exclusive. When procuring from a USAID approved procurement agent, it is necessary to list the specific manufacturer for each line item. Please note only certain procurement agents are able to quote on all pharmaceuticals. GRADE A Wholesalers are the gold standard and are able to quote on any pharmaceutical. GRADE B Wholesalers are able to quote on pharmaceuticals that are manufactured in a country with an SRA or prequalified pharmaceuticals through the WHO Prequalification Programme. Please contact the OHA/SCH for additional information or refer to the following website.

http://transition.usaid.gov/our_work/global_health/aids/TechAreas/treatment/info_approval.pdf

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4. Can USAID funds be used to procure pharmaceuticals from a local or any other manufacturer or wholesaler? Generally, no. Please contact the specific GH office for further guidance on submitting a request for procurement from a manufacturer or wholesaler not included in the aforementioned list. Specifically, malaria-related pharmaceuticals cannot be procured locally with malaria-specific USAID funds.

5. How does ADS 312 apply to investigational pharmaceuticals tested in clinical research trials?

ADS 312 applies to investigational pharmaceuticals and contraceptives; however, the authority to approve or disapprove ADS 312 clearance has been delegated by GH/OHA and GH/PRH to the COR/AOR that is managing the clinical research program in which the investigational agent is being studied. Refer to the ADS 312 Investigational Drugs Action Memo for additional information.

6. Does ADS 312 apply to laboratory EQUIPMENT, such as PIMA machines?

Laboratory equipment, including laboratory consumables and commodities, are not pharmaceuticals and ADS 312 is not applicable (i.e. PIMA machines).

7. Does ADS 312 apply to laboratory REAGENTS and diagnostic tests? Generally, other diagnostic test kits and laboratory reagents are considered pharmaceuticals and require ADS 312 approval.

8. Who are the personnel responsible for granting approval to restricted commodity approval requests?

Please send requests to one of the following individuals with carbon copy to Alicia Briney (abriney@usaid.gov).

- a. Christine Malati (cmalati@usaid.gov) – Pharmaceuticals / Laboratory consumables
- b. Mike Hope (mhope@usaid.gov) – Pharmaceuticals / Laboratory consumables
- c. Jan Miller (jmiller@usaid.gov) – Pharmaceuticals / Laboratory consumables
- d. Jennifer Murphy (jmurphy@usaid.gov) – Malaria-related pharmaceuticals and commodities
- e. Mark Rilling (mrilling@usaid.gov) – Contraceptives and condoms
- f. Erin Seaver (eseaver@usaid.gov) – Contraceptives and condoms