



## Definitions

**Biological:** Products derived from living organisms, including immunobiologicals (such as vaccines), hormones, and blood products. Vaccines and blood products and are considered to be “pharmaceuticals” by USAID [ADS 312](#)

**FDA-Licensed Products:** Products approved by the U.S. Food and Drug Administration (FDA) for market use in the United States, and the product manufacturing facility has been inspected and licensed by the FDA to produce such product. Note: US FDA approved products may be manufactured in a non-US facility provided that the facility has been inspected and meets the US FDA requirements.

**Kit:** A generic term referring to a collection of tools, supplies, or equipment for a specific purpose. Kits often contain USAID restricted commodities such as ORS or LLINs. Kits may be internationally recognized and standardized (e.g., IEHK 2011, UNFPA Reproductive Health Kits) or unique, non-standardized (i.e., hygiene kits, first aid kits, community animal health worker kits).

**Medical Commodities:** A collective term to include pharmaceuticals, consumable medical supplies, and durable medical equipment.

**Medical Equipment (Durable):** These are commodities that may generally be reused after proper cleaning and disinfection have taken place. Medical equipment covers such items including, but not limited to, sphygmomanometers, baby scales, exam tables, etc. USAID/OFDA is interested whether the medical equipment purchased, as well as the quantity and prices are appropriate for the proposed health intervention.

**Medical Supplies (Consumables):** These are commodities that are disposed of after treating a patient. Medical supplies include such items as single-use syringes, bandages, tongue depressor blades, suture materials, and both surgical and exam gloves. USAID/OFDA is interested whether the medical supplies, including quantities and price are appropriate for the proposed health intervention.

**Non-Prequalified Pharmaceutical Wholesalers/Suppliers:** These are pharmaceutical wholesalers or suppliers that have **not** been audited and approved by USAID. Although these suppliers may in fact carry safe, effective, quality human or veterinary pharmaceuticals and vaccines, a case-by-case evaluation must be made. Partners are notified that this is a long process that may take weeks, if not months, to complete. It is dependent upon how quickly required documentation may be provided to USAID/OFDA. Refer to *Annex E - Procedure to Request Approval to use a Non-prequalified Pharmaceutical Wholesaler* on the [OFDA Resources](#) page.

**Oral Rehydrating Salts (ORS):** Oral Rehydrating Salts may be used only in the context of a health sector program. USAID/OFDA does not recommend nor endorse the use of homemade ORS or training in the preparation of homemade ORS.

**Pharmaceutical:** As defined in USAID’s Automated Directives System (ADS) Glossary, 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. The term includes drugs, vitamins, oral rehydration salts (ORS), biologicals, and some in-vitro diagnostic reagents and test kits (e.g., Rapid Diagnostic Tests (RDTs))

are included but devices or their components, parts, or accessories are not. If a kit contains any pharmaceuticals, it is considered a pharmaceutical. Contraceptives, including condoms, are not included in this definition. See [ADS 312](#) for more information.

NOTE: The following are generally NOT funded by USAID/OFDA:

- Antiretroviral medicines (ARVs) or rapid diagnostic tests for HIV/AIDS: Please coordinate with the President's Emergency Program for AIDS Relief ([PEPFAR](#)) program.
- Contraceptives and condoms – Please coordinate with USAID's Office of Population and Reproductive Health (PRH) <http://www.usaid.gov/what-we-do/global-health/family-planning>

**Pre-Qualified Pharmaceutical Wholesalers:** These are pharmaceutical wholesalers that have been audited by USAID/OFDA and found to be able to meet internationally accepted standards for safe, effective and quality pharmaceuticals. This is an ever-expanding list and partners are advised to refer to the updated list of USAID/OFDA pre-qualified pharmaceutical wholesalers, *Annex G*, on the [OFDA Resources](#) page.

**Rapid Diagnostic Tests (RDTs):** A simple, fast way for health workers to test whether a person has a specific disease or condition (i.e., to see if a person with malaria-like symptoms has malaria; or to see if a non-menstruating female is pregnant; or to test for hepatitis, syphilis, typhoid.). (*Note: This definition taken from WHO/WPRO training guide on RDTs; no definition found in USAID ADS.*) RDTs are considered more accurate than presumptive diagnosis. RDTs for the following conditions **must** be included in the pharmaceutical request:

- Malaria (see <http://www.pmi.gov/how-we-work/technical-areas/diagnosis-and-treatment>) for WHO and CDC approved RDTs and treatment products.
- Hepatitis
- Syphilis
- Typhoid
- Cholera
- Pregnancy – both blood (HCG) and urine tests
- Diabetes – blood (finger stick w/glucometer) and urine
- Urine dipstick chemical analysis

**Restricted Goods:** For the purposes of the Medical Commodities including Pharmaceuticals Sub-Sector, the following medical commodities are considered "Restricted Goods" by USAID and must be included in the appropriate sector(s) of the proposal.

- Pharmaceuticals, including:
  - Vaccines
  - Oral Rehydration Salts (ORS)
  - Intravenous (IV) Fluids
- Rapid Diagnostic Tests (RDTs)
- Kits containing pharmaceuticals

**Stringent Regulatory Authority (SRA):** Stringent Drug Regulatory Authority (SRA) means a regulatory authority (in the case of the European Union, both EMEA and nationally competent authorities are included) which is (a) a member of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) (as specified on its [website](#)); or (b) an ICH Observer, being the European Free Trade Association (EFTA) as represented by SwissMedic, Health Canada and World Health Organization (WHO) (as may be updated from time to time); or (c) a regulatory authority associated with an ICH member through a legally binding mutual recognition agreement including Australia, Norway, Iceland and Liechtenstein (as may be updated from time to time).