Definitions

Restricted Goods: For the purposes of the Medical Commodities Sub-Sector, the following medical commodities are considered "Restricted Goods" by USAID and must be included in the Health Sector or Agriculture and Food Security, Veterinary Medicines Sub-Sector, as appropriate in the proposal.

- Pharmaceuticals including
  - Vaccines
  - Oral Rehydration Salts (ORS)
  - Intravenous (IV) Fluids
- Long Lasting Insecticidal Nets (LLINs)

***Pharmaceuticals*:** 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 pharmaceuticals, drugs, medicines, vitamins, and oral rehydration salts (ORS).
NOTE: The following are generally NOT funded by USAID/OFDA:

- Antiretroviral medicines (ARVs) – Please coordinate with the President's Emergency Program for AIDS Relief (PEPFAR) program at www.pepfar.gov/.
- Antimalarial medicines – Please coordinate with the President's Malaria Initiative (PMI) program at www.pmi.gov/.
- Contraceptives and condoms – Please coordinate with USAID's Office of Population and Reproductive Health (PRH) at www.usaid.gov/our_work/global_health/pop/ if you are interested in procuring these commodities for your program.

Biological: Products derived from living organisms, including immunobiologicals (such as vaccines), hormones, and blood products. Vaccines and blood products are considered to be "pharmaceuticals" by USAID.

***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: FDA-approved products may be manufactured in a non-U.S. facility provided that the facility has been inspected and meets the FDA requirements.

Stringent Regulatory Authority (SRA): Stringent Drug Regulatory Authority (SRA) means a regulatory authority, in case of the European Union both the European Medicines Agency (EMA) and national 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) (and 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 (and may be updated from time to time).

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

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, quantities and prices are appropriate. Please provide a separate detailed list of medical supplies with type, number of units, cost/unit and total cost for all medical supplies. The cost must be entered on a separate line in the budget marked accordingly. **Note:** If medical supplies will be provided as gifts in kind (GIK), include the value of the medical supplies in the budget and indicate the source of funding e.g. GIK, partner's own funds etc. Laboratory supplies such as reagents, glassware, rapid diagnostic test kits, solutions, etc. are included as a sub-section of this category.

***Medical Equipment (Durable)*:** These are commodities that may generally be reused after proper cleaning and disinfection have taken place. Medical equipment includes such items including, but not limited to, sphygmomanometers, baby scales, exam tables etc. USAID/OFDA is interested whether the medical equipment purchased, quantity and price is appropriate. Please provide a separate detailed list of medical equipment with type, number of units, cost/unit and total cost for all Medical Equipment. The cost must be entered on a separate line in the budget marked accordingly. **Note:** If medical equipment will be provided as gifts in kind, include the value of the medical equipment in the budget and indicate the source of funding, e.g. GIK, Partner's own funds etc. Laboratory equipment such as microscopes, autoclaves, etc. are included as a sub-section of this category

Long Lasting Insecticidal Nets (LLINs): LLINs are also known as Long Lasting Insecticide Treated Nets (LLITNs) and are USAID restricted commodities. LLINs are used within the context of a health proposal. Partners intending to use LLINs in their projects must familiarize themselves with the Programmatic Initial Environmental Evaluation (P-IEE) on the Partner Resources website at http://www.usaid.gov/what-we-do/working-crises-and-conflict/crisis-response/resources. Specific sections on training and communications, monitoring of effectiveness of use, and insecticide resistance (See Pesticide Annex A: Request for Approval to Purchase LLINs for all the sections) must be included in the proposal language if LLINs will be used in the program.

Medical Kits: 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. In all cases, if a kit is proposed, regardless of type, e.g. Hygiene kit, NFI kit, first-aid kit, Community Animal Health Worker kit, etc.; provide the name of the kit, number of kits being purchased, the supplier of the kit, cost per kit, and the itemized contents list. Include the cost of the kits in a separate, appropriately identified budget line. Universally recognized kits such as the Interagency Emergency Health Kit (IEHK) do not need contents lists to be provided. All non-standard kits must have an itemized contents list to assure USAID/OFDA that no restricted commodities are included.

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

USAID/OFDA Pre-Qualified Pharmaceutical Wholesalers: These are pharmaceutical wholesalers that have been audited and found 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 pre-qualified pharmaceutical wholesalers on the Partner

Resources website at http://www.usaid.gov/what-we-do/working-crises-and-conflict/crisis-response/resources.

USAID/OFDA Non Pre-Qualified Pharmaceutical Wholesalers / Suppliers: These are pharmaceutical wholesalers or suppliers that have **NOT** been audited by USAID or a Stringent Regulatory Authority (SRA). 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; depending on how quickly required documentation may be provided to USAID/OFDA. Please refer to the "Request to use a Non-Pre-Qualified Pharmaceutical Wholesaler – Annex E".