USAID/OFDA Proposal Guidelines

Pharmaceutical & Medical Commodity Guidance

February 2018

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Introduction

In order to purchase medical commodities with USAID/OFDA funds, including medical equipment, medical supplies, and/or human or veterinary pharmaceuticals the following guidance must be followed. All medical commodities are reviewed for appropriateness for the program, for the situation, and for the country. In addition, pharmaceuticals are a specific USAID restricted good and have more rigorous procedures to ensure safety, effectiveness, and quality of the products when provided to beneficiaries.

Definitions

Biological: Products derived from living organisms, including immunobiologicals (such as vaccines), hormones, and blood products.

Disposition: This is what will happen to the pharmaceuticals and medical commodities purchased for the program but remaining when the award is completed. There are three possibilities:

Destruction: The rendering of the pharmaceuticals and/or medical commodities unfit for human or veterinary medical use. This is usually because the commodities have been damaged or are expired.

Donation: The giving of pharmaceuticals and/or medical commodities from one entity (NGO, or PIO, or host nation) to another "free of charge".

Transfer: The movement of pharmaceuticals and/or medical commodities from one project to another within the same organization.

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. U.S. FDA approved products may be manufactured in a non-U.S. facility provided that the facility has been inspected and meets the U.S. 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 oral rehydration salts (ORS) or long-lasting insecticidal treated nets (LLINs). Kits may be

- Internationally recognized and standardized (e.g., Inter-agency Emergency Health Kit, IEHK 2011, or Inter-agency Reproductive Health Kits for Crisis Situations UNFPA 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
- Weighing scales for animals or humans
- Exam tables, and
- Animal hoof knives or trimmers.

USAID/OFDA reviews and approves medical equipment purchases, quantity, and prices to ensure appropriateness for the response situation and the proposed health intervention.

Medical Supplies (Consumables): These are commodities that are disposed of after treating a patient or animal. Medical supplies include such items as

- Single-use syringes
- Bandages
- Tongue depressor blades
- Suture materials, and
- Surgical and exam gloves.

USAID/OFDA reviews and approves medical equipment purchases, quantity, and prices to ensure appropriateness for the response situation and the proposed health intervention.

Non-Prequalified Pharmaceutical Vendors: These are pharmaceutical vendors that have **not** been audited and approved by USAID. Although these vendors may in fact carry safe, effective, quality human or veterinary pharmaceuticals and vaccines, a case-by-case evaluation must be made. This is a long process that may take weeks, if not months, to complete. It is dependent upon how quickly required documentation is provided to USAID/OFDA for review.

Oral Rehydrating Salts (ORS): Oral Rehydrating Salts may be used only in the context of a health sector program. USAID/OFDA does not fund 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, ORS, biologicals, and some in-vitro diagnostic 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; and
- Contraceptives and condoms – Please coordinate with USAID's Office of Population and Reproductive Health (PRH).

Pre-Qualified Pharmaceutical Vendors: These are pharmaceutical vendors 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 a dynamic list and partners are advised to refer to the updated list of USAID/OFDA Prequalified Pharmaceutical Vendors later in this document.

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). This definition is taken from WHO/WPRO training guide on

RDTs as USAID ADS does not define the term. RDTs are considered more accurate than presumptive diagnosis. RDTs for the following conditions **must** be included in the pharmaceutical request:

- Malaria - See the President's Malaria Initiative for WHO and CDC approved RDTs and treatment products;
- Syphilis; and
- Cholera.

Restricted Goods: For the purposes of the Pharmaceuticals and other Medical Commodities 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), and
  - Intravenous (IV) Fluids;
- Rapid Diagnostic Tests (RDTs) – only Cholera, Malaria, and Syphilis; and
- All kits containing pharmaceuticals.

Stringent Regulatory Authority (SRA): A drug regulatory body that closely resembles the U.S. Food and Drug Administration (FDA) in standards utilized in its operations. Currently, countries that participate in the International Conference on Harmonization (ICH) are considered stringent regulatory authorities. The ICH regulatory bodies include:

- U.S. FDA;
- Japanese Ministry of Health, Labor, and Welfare;
- European Agency for the Evaluation of Medicinal Products (EMEA) centralized procedure;
- European Free Trade Area (represented by the Swiss Medic);
- European Union member states admitted prior to 1996; and
- Australian Therapeutic Goods Administration (TGA).

The Canadian drug regulatory authority, the Therapeutic Products Directorate, Health Canada, is an observer to the ICH and is also considered a stringent regulatory authority. Other countries may be considered having a stringent regulatory body if they have implemented ICH guidelines and resemble the U.S. FDA in operation, but would be considered on a case-by-case basis.

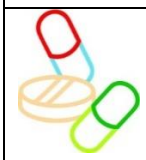
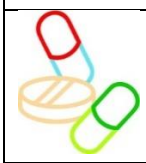
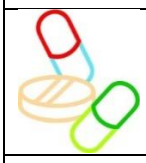
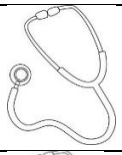
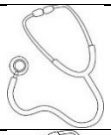
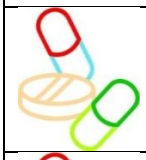
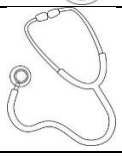
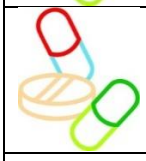
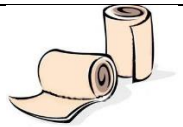
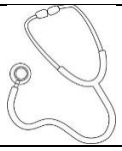
Decision Flow: Applicable for All Medical Commodity Types

– Human and Veterinary

The following is a pictorial diagram to assist in determining what template must be submitted.

1. Read the chart from left to right. E.g., if you are ONLY requesting to procure pharmaceuticals, reading left to right, you would ONLY complete and submit the template tab for Pharm, RDTs, & Kits.
2. However, if you are requesting to procure pharmaceuticals AND medical equipment, you would complete and submit the template tabs for Pharm, RDT, & Kits AND med equipment.

If you are not requesting to procure any pharmaceuticals, medical equipment, and/or medical supplies, you do not need to complete and submit any templates.

Pharmaceuticals 	**Med Equipment** 	**Med Supplies** 		**Complete these parts of Pharmaceutical and Medical Commodities Templates**
All Dosage Forms (oral, topical, injectable) Human AND Veterinary	**Durable goods for repeated use (stethoscopes, implant devices) Human AND Veterinary**	**One-time use; disposable (syringes, gauze) Human AND Veterinary**		
[None]	[None]	[None]		[None]
				Pharmaceutical Templates Tab Pharm, RDT & kits
				Pharmaceutical Templates Tab Pharm, RDTs & Kits
				Pharmaceutical Templates Tab Pharm, RDTs, & Kits
				Pharmaceutical Templates Tab Med Equipment
				Pharmaceutical Templates Tab Pharm, RDTs, & Kits
				Pharmaceutical Templates Tab Pharm, RDTs, and Kits
				Pharmaceutical Templates Tab Med Equipment
				Pharmaceutical Templates Tab Med Supplies

Procedures to Purchase Pharmaceuticals and Medical Commodities

In order to purchase medical commodities for humans or animals with USAID/OFDA funds, including medical supplies, medical equipment pharmaceuticals and/or rapid diagnostic tests (RDTs), the following guidance must be followed in accordance with USAID's Agency Automated Directives System 312 (ADS 312). The total cost of each medical commodity type must also be reported in a separate budget line.

For requests to purchase human or veterinary pharmaceuticals, RDTs, and/or kits containing pharmaceuticals, the following is required:

1. All pharmaceuticals must be in accordance with The USAID/OFDA Essential Medicines List for Humans found later in this document. Review the products on the list. It contains three rapid diagnostic tests and several internationally recognized and standardized kits that contain pharmaceuticals.
2. You must provide an itemized list of the pharmaceutical products including any rapid diagnostic tests, and/or any kits that contain pharmaceuticals (e.g., IEHK 2011, PEP kit, UNFPA kit 3, First Aid kits, etc.) on a fillable spreadsheet. See the Pharmaceuticals and Medical Commodities Templates for a format which will address necessary fields. The template contains several tabs:
    - The *Overview* tab describes the templates,
    - The *Pharm, RDT, & Kit* tab should be filled out when requesting procurement of these items,
    - The *Med Equipment* tab should be filled out when requesting procurement of medical equipment,
    - The *Med Supplies* tab should be filled out when requesting procurement of medical supplies, and
    - The *Disposition* tab should be filled out at the end of an award when describing how any remaining commodities will be handled.

    a. Using the *Pharm, RDT, & Kit* tab of the template, the pharmaceuticals list must be identified with your organization's
        - Name
        - Project title
        - Country, and
        - Vendor
        - Total requested for procurement of the pharmaceuticals, exclusive of transportation or handling, and
        - Assurance that the partner is following all host nation policies for importation of pharmaceuticals, that the host nation has approved of the importation without taxation or undue delay for use in the humanitarian response and date.

    The list itself must include
        - Name of each pharmaceutical by international generic name;
        - Strength and dosage form;
        - Reason for use of the pharmaceutical within the program. In veterinary requests include species of animal as well as condition to be treated. I.e., oxytetracycline for foot rot in cattle;

- Quantity. This is the number of unit-of-issue packages to be requested;
- Unit-of-issue. This is how the vendor sells the product - bottle of 10, 30, 100 or 1000 tablets; bottle of 480ml; 10 vials each 2ml of an injectable product;
- Cost per unit-of-issue. In USD (how much does each bottle of 10, 30, 1000 of tablets, or bottle of 480ml; or 10 vials each 2ml of an injectable cost. Not how much is each tablet;
- Extended cost in USD. Quantity multiplied by cost per unit of issue; and
- Total cost for all pharmaceuticals on the list in USD.

b. If a partner seeks USAID/OFDA funds to purchase a kit that contains pharmaceuticals (e.g., IEHK 2017, PEP kit, UNFPA kit 3, First Aid kits, Hygiene kit, NFI kit, etc.), the
   - Name of the kit
   - Number of kits being purchased
   - Cost per kit, and
   - Itemized contents list must be provided to USAID/OFDA.

   Universally standardized and recognized kits such as the Interagency Emergency Health Kit (IEHK,2017) do not require a list of contents. All non-standard kits (I.e., hygiene kits, NFI kits, first aid kits) must have an itemized contents list.

3. If you are requesting to use a non-USAID/OFDA prequalified pharmaceutical vendor, in addition to all of the above information, documentation is required supporting the safety, efficacy, and quality of the products and the vendor. The process to approve a non-USAID/OFDA prequalified pharmaceutical vendor may take weeks or months depending on the information that is provided to USAID/OFDA. The following documentation (in English) must be submitted:
   a. Complete address and contact information of the pharmaceutical vendor;
   b. Website, if available;
   c. Product catalog and price list;
   d. Organizational chart (list of principals and their titles);
   e. Government documents authorizing the sale of pharmaceuticals (current licenses and/or permits);
   f. A list of the organizations that have inspected the pharmaceutical vendor within the past 24 months **and the results of inspection(s);**
   g. A copy of the vendor's standard operating procedures related to their quality assurance program;
   h. List of the individuals responsible for the quality assurance of pharmaceuticals;
   i. Procedures or process used to select inventory of the vendor;
   j. Availability of computerized invoices, packing lists with batch numbers and delivery notices;
   k. Availability of certificates of analysis for each batch of each pharmaceutical product purchased;
   l. Assurance from the vendor that all pharmaceuticals meet international standards for quality, safety, and efficacy;
   m. Assurance that the expiration policy states that no pharmaceuticals will be sold within 12 months prior to the expiration date; and

n. Photographs of exterior of warehouse, interior storage areas, signage, windows, delivery and shipping docks, cold storage facility, temperature monitors, shelving systems, and pest control measures.

For requests to purchase human or veterinary medical supplies and/or medical equipment, please provide a separate itemized list for each category of medical commodity requested (e.g., medical supplies on one list, medical equipment on another). Each list must be identified with the partner's name, project title, total cost of the commodity type, and date of submission of the list. See the Pharmaceuticals and Medical Commodities Templates for a format which will address necessary fields. Each list must include the following information:

1. Medical supplies (consumables). Laboratory supplies (such as reagents, glassware, solutions, etc.) are included in this category. The cost must be entered on a separate line in the budget and marked accordingly. Using the *Med Supplies* tab of the template, provide a detailed list of medical supplies with
    a. Item name
    b. Quantity
    c. Cost per unit (USD), and
    d. Total cost for all medical supplies.
2. Medical equipment (durable). Laboratory equipment (such as microscopes, autoclaves, etc.) is included in this category. The cost must be entered on a separate line in the budget and marked accordingly. Using the *Med Equipment* tab of the template, provide a detailed list of medical equipment with
    a. Item name
    b. Quantity
    c. Cost/unit (USD), and
    d. Total cost for all medical equipment.

The USAID/OFDA Essential Medicines List for Humans

USAID/OFDA initially developed an Essential Medicines List (OFDA EML) in 2013. It was designed to simplify the pharmaceutical product selection process by NGO and PIO partners and to expedite the USAID/OFDA review and approval of the pharmaceuticals requested. Each revision is based upon USAID/OFDA's experiences with the original list. The revisions attempt to improve partners' abilities to identify and select appropriate pharmaceuticals for their USAID/OFDA-supported health programs. The revised USAID/OFDA EML will continue to

1. Simplify the pharmaceutical selection process,
2. Expedite the pharmaceutical approval process, and
3. Maximize USAID/OFDA resources to provide the greatest amount of assistance to the greatest number of beneficiaries possible.

USAID/OFDA's health programs are based on the concept of primary health care through which essential health care is accessible to individuals, families, and the community. The primary focus of the latest revision reviewed therapeutic changes and product experience, while ensuring appropriateness for use in the majority of USAID/OFDA-supported health programs. Every health program should have an EML. This does not mean all pharmaceuticals must be available at every level of care or that all the products on the USAID/OFDA EML are appropriate for every program.
A pharmaceutical product's inclusion on the USAID/OFDA EML does NOT convey blanket approval for use.

Pharmaceuticals requested for USAID/OFDA-supported health programs are reviewed for appropriateness for the health intervention, the situation, and the country in addition to safety, efficacy, and quality.

USAID/OFDA does not traditionally support pharmaceuticals supplied by national programs such as the expanded program for immunization (EPI) or programs focusing on family planning, HIV/AIDS, or tuberculosis. Pharmaceutical support for some of these areas may be appropriate for USAID/OFDA programs on a case-by-case justification basis. Where appropriate, USAID/OFDA supports partners obtaining their pharmaceutical needs through use of the most current internationally standardized and recognized pharmaceutical kits (e.g., IEHK 2011, or Interagency Reproductive Health kits for Use in Crisis situations, 2010).

As background, the original USAID/OFDA EML was a subset of the

- WHO *Model List of Essential Medicines*,
- WHO Interagency Emergency Health Kit (IEHK) contents 2011,
- UNFPA/Interagency Reproductive Health Kit #3- Post-Rape/Post Exposure Prophylaxis (PEP) recommendations and kit, and
- UNHCR *Essential Medicines and Medical Supplies: Policy and Guidance* (2011).

The revised EML is based on review of changes to the

- *WHO Model List of Essential Medicines* (19th list, April 2015),

- The revised contents of the WHO IEHK 2011 Basic, Supplementary 2015-Malaria, and PEP modules; and
- UNFPA Interagency Reproductive Health Kits.

The USAID/OFDA EML is expected to treat the majority of the medical conditions encountered in USAID/OFDA-supported health programs based on the medical conditions identified by our partners and use of the list for the past years.

Using the EML

The 2018 USAID/OFDA *Proposal Guidelines* provide information on what is required when submitting a request to USAID/OFDA to purchase pharmaceuticals. The procedures to procure pharmaceuticals are included in this guidance document. A sample template combining the letter and the list are included in the USAID/OFDA Pharmaceutical Templates.

You must base your selection of pharmaceuticals on the USAID/OFDA EML. Please note the list of pharmaceutical products which have a restricted use indication. This is the ONLY indication that will be acceptable for these products unless otherwise requests and approved.

If you wish to purchase pharmaceuticals that are not on the USAID/OFDA EML or request an alternative use for one designated as a restricted-use product, you must request an exception providing the following information:

1. Submit a request explaining the need based upon a specific disease condition and data.
2. Your organization's headquarters-level responsible physician must sign, as indicated in the USAID/OFDA *Proposal Guidelines*.
3. Within your request, separate justifications are required for each pharmaceutical product for which you seek exemption.
4. Requests for exception (and supporting justifications) must be submitted each time the procurement of the product is requested.
5. Review of the exception(s) may slow the overall approval process and does not guarantee approval. If exception is approved; you may proceed with procurement.
6. You must track in your program performance reports the use of any product with a restricted use indication and/or any non-USAID/OFDA EML product including the number of patients treated for the specific indication.

ALPHABETICAL LISTING of PHARMACEUTICAL PRODUCTS

Restricted products highlighted in yellow

Product Name	*EML Category Number(s)*
Acetazolamide	EML 21
Acetylsalicylic acid	EML 2 1; EML 12
Acyclovir	EML 6 4; EML 21
Adrenaline	see Epinephrine
Albendazole	EML 6 1
Amitriptyline	EML 2 3; EML 24
Amlodipine	EML 12
Amodiaquine	EML 6 5 3
Amoxicillin	EML 6 2
Amoxicillin + clavulanic acid	EML 6 2
Amphotericin B	EML 6 3; EML 6 5 2
Ampicillin	EML 6 2
Artemether	EML 6 5 3
Artemether + lumefantrine	EML 6 5 3
Artesunate	EML 6 5 3
Artesunate + amodiaquine	EML 6 5 3
Artesunate + mefloquine	EML 6 5 3
Ascorbic acid	EML 27
Atenolol	EML 12
Atracurium	EML 20
Atropine	EML 1 3; EML 4; EML 21
Azithromycin	EML 6 2
Beclomethasone	EML 25
Benzathine benzylpenicillin	EML 6 2
Benznidazole	EML 6 5 4
Benzyl benzoate	EML 13
Benzylpenicillin	EML 6 2
Betamethasone	EML 13
Bisoprolol	EML 12
Budesonide	EML 25
Bupivacaine	EML 1 2
Calamine	EML 13
Calcium gluconate	EML 4
Carbamazepine	EML 5; EML 24
Carvedilol	EML 12
Cefalexin	EML 6 2
Cefazolin	EML 6 2
Cefixime	EML 6 2
Ceftriaxone	EML 6 2
Charcoal, activated	EML 4
Chloramphenicol	EML 6 2
Chloroquine	EML 6 5 3
Chlorpheniramine	EML 3
Chlorpromazine	EML 24
Cholera Rapid Diagnostic Test (RDT)	EML 0
Ciprofloxacin	EML 6 2

Product Name	*EML Category Number(s)*
Clopidogrel	EML 12
Clotrimazole	EML 6 3
Cloxacillin	EML 6 2
Cyclopentolate	EML 21
Dexamethasone	EML 2 3; EML 3; EML 17
Diarrheal Disease Kit (IDDK), Basic/drugs	EML 00
Diarrheal Disease Kit (IDDK), ORS	EML 00
Diarrheal Disease Kit (IDDK), Infusion	EML 00
Diazepam	EML 2 3; EML 5; EML 24
Dicloxacillin	EML 6 2
Diethylcarbamazine	EML 6 1
Digoxin	EML 12
Diloxanide	EML 6 5 1
Docusate	EML 2 3; EML 17
Doxycycline	EML 6 2; EML 6 5 3
Eflornithine	EML 6 5 4
Enalapril	EML 12
Enoxaparin	EML 10
Epinephrine	EML 3;EML 12; EML 25
Ergometrine	EML 22
Erythromycin	EML 6 2
Ferrous salt	EML 10
Ferrous salt + folic acid	EML 10
Fluconazole	EML 6 3

Fluorescein	EML_14
Fluoxetine	EML_2_3; EML_24
Fluphenazine	EML_24
Folic acid	EML_10
Furosemide	EML_12; EML_16
Gentamicin	EML_6_2; EML_21
Glibenclamide (glyburide)	EML_18
Gliclazide	EML_18
Glucagon	EML_18
Glucose	EML_26
Glucose with sodium chloride	EML_26
Glyceryl trinitrate	EML_12
Haloperidol	EML_2_3; EML_24
Halothane	EML_1_1
Heparin	EML_10
Homatropine	EML_21
Hydralazine	EML_12
Hydrochlorothiazide (HCTZ)	EML_12;EML_16
Hydrocortisone	EML_3; EML_13
Hydroxocobalamin	EML_10
Hyoscine	EML_2_3; EML_17
Product Name	*EML Category Number(s)*
IDDK, Basic module – Drugs	EML_00
IDDK, ORS module	EML_00
IDDK, Infusion module	EML_00
IEHK, 2011 – Basic	EML_00
IEHK, 2015– Supplementary	EML_00
Ibuprofen	EML_2_1
Insulin (soluble)	EML_18
Insulin, intermediate acting	EML_18
Ipratropium bromide	EML_25
Isoflurane	EML_1_1
Isosorbide dinitrite	EML_12
Italian Emergency Trauma Kit	EML_00

Ivermectin	EML_6_1
Ketamine	EML_1_1
Levothyroxine	EML_18
Lidocaine	EML_1_2; EML_12
Lidocaine + epinephrine	EML_1_2
Lithium carbonate	EML_24
Loratadine	EML_3
Lorazepam	EML_5
Magnesium sulfate	EML_5
Malaria Rapid Diagnostic Test (RDT)	EML_0
Mebendazole	EML_6_1
Mefloquine	EML_6_5_3
Meglumine antimoniate	EML_6_5_2
Melarsoprol	EML_6_5_4
Metformin	EML_18
Methyldopa	EML_12
Metoclopramide	EML_2_3; EML_17
Metoprolol	EML_12
Metronidazole	EML_6_2;EML_6_5_1
Miconazole	EML_13
Midazolam	EML_1_3; EML_2_3; EML_5
Miltefosine	EML_6_5_2
Misoprostol	EML_22
Morphine	EML_1_3; EML_2_2
Mupirocin	EML_13
Naloxone	EML_4
Neostigmine	EML_20
Niclosamide	EML_6_1
Nifedipine	EML_22
Nifurtimox	EML_6_5_4
Nitrofurantoin	EML_6_2
Nitroglycerin	See Glyceryl trinitrate
Nitrous oxide	EML_1_1
Nystatin	EML_6_3
Ofloxacin	EML_21
Omeprazole	EML_17
Product Name	*EML Category Number(s)*

Ondansetron	EML_2_3;EML_17
Oral rehydration salts (ORS)	EML_17; EML_26
Oxygen	EML_1_1
Oxytocin	EML_22
Paracetamol	EML_2_1
Paromomycin	EML_6_5_2
Pentamidine	EML_6_5_4
Permethrin	EML_13
Phenobarbital	EML_5
Phenoxymethylpenicillin	EML_6_2
Phenytoin	EML_5
Phytomenadione	EML_10
Pilocarpine	EML_21
Potassium Chloride	EML_26
Potassium iodide	EML_18
Potassium permanganate	EML_13
Praziquantel	EML_6_1
Prednisolone	EML_3; EML_21
Prednisone	EML_3
Primaquine	EML_6_5_3
Procaine benzylpenicillin	EML_6_2
Proguanil	EML_6_5_3
Propofol	EML_1_1
Propylthiouracil	EML_18
Protamine sulfate	EML_10
Pyrantel	EML_6_1
Quinine	EML_6_5_3
Ranitidine	EML_17
Retinol	EML_27
Risperidone	EML_24
Salbutamol	EML_25
Selenium sulfide	EML_13
Senna	EML_2_3; EML_17
Silver sulfadiazine	EML_13
Simvastatin	EML_12
Sodium chloride	EML_26
Sodium hydrogen carbonate	EML_26
Sodium lactate compd solution	EML_26
Sodium stibogluconate	EML_6_5_2
Spironolactone	EML_12; EML_16
Sulfadoxine+pyrimethamine	EML_6_5_3
Sulfamethoxazole+trimethoprim	EML_6_2
Suramin sodium	EML_6_5_4
Suxamethonium (succinylcholine)	EML_20
Syphilis Rapid Diagnostic Test (RDT)	EML_0
Terbinafine	EML_13
Tetracaine	EML_21
Tetracycline	EML_21
Thiopental	EML_1_1
Timolol	EML_21

Product Name	*EML Category Number(s)*
Tinidazole	EML_6_5_1
Tranexamic acid	EML_10
Trauma Kit A	EML_00
Triclabendazole	EML_6_1
Trimethoprim	EML_6_2
Tropicamide	EML_14
UNFPA kit #3	EML_00
UNFPA kit #5	EML_00
UNFPA kit #6B	EML_00
UNFPA kit #11B	EML_00
UNFPA kit #12	EML_00
Valproic acid	EML_5;EML_24
Vecuronium	EML_20
Verapamil	EML_12
Warfarin	EML_10
Water for injection	EML_26
Zinc sulfate	EML_17

PRODUCTS RESTRICTED FOR ONLY SPECIFIC INDICATION

The following pharmaceuticals are restricted for use only for the specified indications. These indications were selected on the basis of current and estimated future public health relevance, and potential for safe and cost-effective treatment. The products may only be used for the specified condition, unless express written approval is otherwise given.

	Pharmaceutical Product	Restricted Use Indication
1	Azithromycin	For single-dose treatment of genital *Chlamydia trachomatis* and trachoma only; unless obtained as part of UNFPA kit #5 (and then to be used as indicated in the kit)
2	Cefazolin	For surgical prophylaxis and post-surgical infections
3	Cefixime	For single-dose treatment of uncomplicated anogenital gonorrhea only; unless obtained as part of UNFPA kit #5 (and then to be used as indicated in the kit)
4	Hydralazine	For acute management of severe pregnancy-induced hypertension
5	Magnesium sulfate	For eclampsia and severe pre-eclampsia
6	Methyldopa	For management of pregnancy-induced hypertension
7	Misoprostol	a. *Oral tablet* - for use of incomplete abortion and miscarriage, and for prevention of postpartum hemorrhage where oxytocin is not available or cannot be safely used b. *Vaginal tablet* - for use of induction of labor where appropriate facilities are available

Kits containing pharmaceuticals – Internationally recognized & standardized
Interagency Diarrheal Disease Kit (IDDK), Basic module - Drugs
Interagency Diarrheal Disease Kit (IDDK), ORS module
Interagency Diarrheal Disease Kit (IDDK), Infusion module
Interagency Emergency Health Kit (IEHK)2011, Basic
Interagency Emergency Health Kit (IEHK) 2015, Supplementary – *(contains medicines, infusion, patient PEP, and malaria items)*
Inter-Agency Reproductive Health Kits for Use in Crisis situations, 5th edition, 2010 – (UNFPA) Kit #3
Inter-Agency Reproductive Health Kits for Use in Crisis situations, 5th edition, 2010 – (UNFPA) Kit #5
Inter-Agency Reproductive Health Kits for Use in Crisis situations, 5th edition, 2010 – (UNFPA) Kit #6B
Inter-Agency Reproductive Health Kits for Use in Crisis situations, 5th edition, 2010 – (UNFPA) Kit #11B
Inter-Agency Reproductive Health Kits for Use in Crisis situations, 5th edition, 2010 – (UNFPA) Kit #12
Italian Emergency Trauma Kit A (Trauma kit A)
Rapid Diagnostic Tests (RDTs)
Cholera
Malaria
Syphilis
1. Anesthetics
1.1 General anesthetics and oxygen
Halothane
Isoflurane
Ketamine
Nitrous oxide
Oxygen
Propofol (or thiopental as alternative)
1.2 Local anesthetics
Bupivacaine
Lidocaine
Lidocaine + epinephrine (adrenaline)
1.3 Preoperative medication and sedation for short-term procedures
Atropine
Midazolam
Morphine
2. Medicines for pain and palliative care
2.1 Non-opioids and non-steroidal anti-inflammatory medicines (NSAIMs)
Acetylsalicylic acid
Ibuprofen
Paracetamol
2.2 Opioid analgesics
Morphine
2.3 Medicines for other common symptoms in palliative care

Amitriptyline
Dexamethasone
Diazepam
Docusate
Fluoxetine
Haloperidol
Hyoscine
Metoclopramide
Midazolam
Ondansetron
Senna
3. Antiallergics and medicines used in anaphylaxis
Chlorpheniramine
Dexamethasone
Epinephrine (adrenaline)
Hydrocortisone
Loratadine
Prednisolone
Prednisone
4. Antidotes and other substances used in poisonings
Atropine
Calcium gluconate
Charcoal, activated
Naloxone
5. Anticonvulsants/antiepileptics
Carbamazepine
Diazepam
Lorazepam
Magnesium sulfate - Restricted only for use in eclampsia and severe pre-eclampsia
Midazolam
Phenobarbital
Phenytoin
Valproic acid (sodium valproate)
6. Anti-infective medicines
6.1 Anthelminthic
Albendazole
Diethylcarbamazine
Ivermectin
Mebendazole
Niclosamide
Praziquantel
Pyrantel
Triclabendazole
6.2 Antibacterials
Amoxicillin
Amoxicillin + clavulanic acid
Ampicillin
Azithromycin – Restricted only for use in single-dose treatment of genital *Chlamydia*

trachomatis and of trachoma
Benzathine benzylpenicillin
Benzylpenicillin
Cefalexin
Cefazolin – Restricted only for use in surgical prophylaxis and surgical related infections
Cefixime – Restricted only for use in single-dose treatment of uncomplicated anogenital gonorrhea
Ceftriaxone
Chloramphenicol
Ciprofloxacin
Clindamycin
Cloxacillin
Dicloxacillin
Doxycycline
Erythromycin
Gentamicin
Metronidazole
Nitrofurantoin
Phenoxymethylpenicillin
Procaine benzylpenicillin
Sulfamethoxazole + trimethoprim (SMZ/TMP)
Trimethoprim
6.3 Antifungal medicines
Amphotericin B
Clotrimazole
Fluconazole
Nystatin
6.4 Antiviral medicines
Acyclovir
Antiretrovirals (ARVs) - ONLY complete post rape (PEP) kits are authorized for procurement and use. Only US FDA approved or tentatively-approved antiretrovirals are acceptable. Antiretrovirals are only for post rape or body fluid/occupational exposure. This ensures complete treatment protocol (and meds) are obtained and in appropriate quantities. Partners may procure either UNFPA post rape kit #3 or IEHK 2015, PEP module
6.5 Antiprotozoal medicines
6.5.1 Antiamoebic and antigiardiasis medicines
Diloxanide
Metronidazole
Tinidazole
6.5.2 Antileishmaniasis medicines
Amphotericin B
Miltefosine
Paromomycin
Sodium stibogluconate or meglumine antimoniate
6.5.3 Antimalarial medicines – All anti-malarials must be included in the WHO malaria treatment guidance and meet the following: (1) US FDA or Stringent Regulatory Authority (SRA) approval; or (2) Prequalification by the WHO; or (3) Purchased from a

USAID/OFDA pre-qualified pharmaceutical wholesaler. Specific treatments must be in accordance with global and national treatment guidelines and resistance patterns. Please note requirements on use of specific products in combination/together. Medicines for the treatment of *P. falciparum* malaria cases must be used in combination.
Amodiaquine - Only in combination with artesunate 50 mg
Artemether - Only for the management of severe malaria
Artemether + lumefantrine
Artesunate - To be used in combo w/either amodiaquine, mefloquine, or sulfadoxine + pyrimethamine
Artesunate + Amodiaquine
Artesunate + mefloquine
Chloroquine - Restricted use only for the treatment of P.vivax infection where not resistant
Doxycycline - In combination with quinine
Mefloquine - Only in combination with artesunate 50mg
Primaquine - Only to achieve radical cure of P.vivax and P.ovale infections, given for 14 days
Quinine - Only for management of severe malaria, and in combination with doxycycline
Sulfadoxine + pyrimethamine - Only in combination with artesunate 50 mg
Proguanil – Only in combination with chloroquine
6.5.4 Antitrypanosomal medicines
Benznidazole
Eflornithine – Treatment of *Trypanosoma brucei gambiense*
Melarsoprol
Nifurtimox – Used in combination with eflonithine, for treatment of *Trypanosoma brucei gambiense*
Pentamidine – Only for treatment of *Trypanosoma brucei gambiense*
Suramin sodium – Only for treatment of initial phase of *Trypanosoma brucei rhodesiense*
7. Antimigraine medicines - Migraine specific products are not supported in USAID/OFDA programs
8. Antineoplastics and immunosuppressives - None on USAID/OFDA EML
9. Antiparkinsonism medicines - None on USAID/OFDA EML
10. Medicines affecting the blood
Enoxaparin
Ferrous salt
Ferrous salt + folic acid
Folic acid
Heparin sodium
Hydroxocobalamin
Phytomenadione
Protamine sulfate
Tranexamic acid
Warfarin
11. Blood products of human origin and plasma substitutes - None on USAID/OFDA EML
12. Cardiovascular medicines

Acetylsalicylic acid
Amlodipine
Atenolol
Bisoprolol
Carvedilol
Clopidogrel
Digoxin
Enalapril
Epinephrine (adrenaline)
Furosemide
Glyceryl trinitrate (nitroglycerin)
Hydralazine - Restricted only for use in acute management of severe pregnancy-induced hypertension
Hydrochlorothiazide
Isosorbide dinitrate
Lidocaine
Lisinopril
Methyldopa - Restricted only for use in the management of pregnancy-induced hypertension
Metoprolol
Simvastatin
Spironolactone
Verapamil
13. Dermatological medicines - topical
Betamethasone
Benzyl benzoate
Calamine
Hydrocortisone
Miconazole
Mupirocin
Permethrin
Potassium permanganate
Selenium sulfide
Silver sulfadiazine
Terbinafine
14. Diagnostic agents - ophthalmic preparations
Fluorescein
Tropicamide
15. Disinfectants and antiseptics - Products such as alcohol-based hand rubs, chlorhexidine, chloroxylenol, ethanol, glutaral, polyvidone iodine, chlorine base compound must NOT be included in the pharmaceutical list but rather in the Medical Supply list.
16. Diuretics
Furosemide
Hydrochlorothiazide
Spironolactone
17. Gastrointestinal medicines
Dexamethasone

Docusate
Hyoscine
Metoclopramide
Omeprazole
Ondansetron
Oral rehydration salts (ORS) – must be specified as the low osmolarity formulation Powder for dilution: in 200ml; 500ml; and 1L Must be the following composition: Glucose 75mEq or mmol/L Sodium 75mEq or mmol/L Chloride 65 mEq or mmol/L Potassium 20mEq or mmol/L Citrate 10 mmol/L Osmolarity 245 mOsm/L Glucose 13.5 g/L Sodium chloride 2.6 g/L Potassium chloride 1.5 g/L Trisodium citrate dihydrate+ 2.9/L +trisodium citrate dihydrate may be replaced by sodium hydrogen carbonate (sodium bicarbonate) 2.5g/L. However – must only be used when product will be immediately consumed.
Ranitidine
Senna
Zinc sulfate – Only as adjunct to ORS
18. Hormones - Other endocrine medicines and contraceptives
Glibenclamide
Gliclazide
Glucagon
Insulin (soluble)
Intermediate-acting Insulin
Levothyroxine
Metformin
Potassium iodide
Propylthiouracil
19. Immunologicals
Vaccines – USAID/OFDA supports WHO and UNICEF for the procurement of vaccines. WHO and UNICEF must identify the need and request vaccines on a case-by-case basis. Other USAID/OFDA partners must coordinate with WHO and/or UNICEF for procurement of vaccines.
20. Muscle relaxants (peripherally-acting) and cholinesterase inhibitors
Atracurium
Neostigmine
Suxamethonium (succinylcholine)
Vecuronium
21. Ophthalmological preparations
Acetazolamide
Acyclovir ointment

Atropine
Cyclopentolate
Gentamicin
Homatropine
Ofloxacin
Pilocarpine
Prednisolone
Tetracaine
Tetracycline
Timolol
22. Oxytocics and antioxytocics
Ergometrine
Misoprostol Oral Tablet - Restricted only for use in cases of incomplete abortion and miscarriage, and for prevention of postpartum hemorrhage where oxytocin is not available or cannot be safely used. Vaginal tablet - Restricted only for use of induction of labor where appropriate facilities are available.
Nifedipine
Oxytocin
23. Peritoneal dialysis solution - None on USAID/OFDA EML
24. Medicines for mental and behavioral disorders
Amitriptyline
Carbamazepine
Chlorpromazine
Diazepam
Fluoxetine
Fluphenazine
Haloperidol
Lithium carbonate
Risperidone
Valproic acid (sodium valproate)
25. Medicines acting on the respiratory tract
Beclomethasone
Budesonide
Epinephrine (adrenaline)
Ipratropium bromide
Salbutamol
26. Solutions correcting water, electrolyte, and acid-base disturbances – oral and intravenous
Glucose
Glucose with sodium chloride
Oral rehydration salts - See Section 17.5.1 for specific content formulation
Potassium chloride
Sodium chloride
Sodium hydrogen carbonate
Sodium lactate, compound solution
Water for injection

27. Vitamins and minerals
Ascorbic acid
Retinol
28. Ear, Nose and Throat conditions in children - None on USAID/OFDA EML
29. Specific medicines for neonatal care - None on USAID/OFDA EML
30. Medicines for disease of joints - None on USAID/OFDA EML

USAID/OFDA Prequalified Pharmaceutical Vendors

USAID/OFDA has recognized 11 international pharmaceutical vendors as consistently able to provide safe, effective, and quality essential medicines, and other medical commodities.

These vendors are listed in alphabetical order and no endorsement is made of any particular vendor:

1. Action Medeor, Germany www.medeor.de/en/
2. AmstelFarma, Netherlands www.amstelfarma.nl
3. ASRAMES, Democratic Republic of Congo www.asrames.com/en/
4. CHMP Kenya, Kenya www.chmp-kenya.org
5. IDA Foundation, Netherlands www.idafoundation.org
6. IMRES, Netherlands info@imres.nl
7. Medical Export Group (MEG), Netherlands www.meg.nl
8. Mission for Essential Drugs and Supplies (MEDS), Kenya www.meds.or.ke
9. MissionPharma, Denmark www.missionpharma.com
10. Munir Sukhtian Group (MSG) Company**, Jordan Lhamdan@sukhtian.com.jo
    **Human and Veterinary products
11. UNICEF, Denmark www.unicef.org