



OFDA Essential Medicines List (OFDA EML)

September 2013

For

Adults and Children

Introducing the USAID/OFDA Essential Medicines List

USAID/OFDA has developed an Essential Medicines List (OFDA EML). It is envisioned that use of this list will simplify the pharmaceutical selection process by NGO and PIO partners – and expedite the OFDA review and approval of the pharmaceuticals requested.

The OFDA EML will

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

BACKGROUND:

The OFDA EML derives from the WHO *Model List of Essential Medicines*, the contents of the WHO Interagency Emergency Health Kit (IEHK) 2011, UNFPA's Post-Exposure Prophylaxis (PEP) recommendations and kit, and the UNHCR *Essential Medicines and Medical Supplies: Policy and Guidance* (2011). The OFDA EML may be viewed as a subset of the WHO *Model List of Essential Medicines*. Based on the medical conditions identified by our partners, the OFDA EML is expected to treat 90 to 95% of the medical conditions encountered. By selecting pharmaceuticals from the OFDA EML, you are assured that the pharmaceuticals will be considered appropriate for response.

PROCEDURES:

The October 2012 OFDA *Guidelines for Proposals* provide information on what is required from partners when submitting a request to OFDA to purchase pharmaceuticals. Annex D of the OFDA *Guidelines* provides the accepted format for listing the requested pharmaceuticals.

Partners may now refer to the OFDA EML for a list of approved pharmaceuticals. Please note the acceptable indications (uses) within the EML, based on the WHO recommendations.

If you wish to purchase pharmaceuticals that are NOT on the OFDA EML, you may request an exception. The exception requires justification signed by your organization's headquarters-level responsible physician, as indicated in the OFDA *Guidelines*. Please note that a separate request for each pharmaceutical exception is needed and that the review of the exception(s) may slow the overall approval process and does not guarantee approval.

OFDA Essential Medicines List (June 2013)

Explanatory Notes

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. Essential medicines play a crucial role in the prevention and control of diseases. OFDA has therefore developed an essential medicine list (EML), based on WHO's *Model List of Essential Medicines* March 2011 with additional consideration of the Interagency Emergency Health Kit 2011 (basic and supplementary components), UNFPA's Post-Exposure Prophylaxis (PEP) recommendations and kit, and UNHCR *Essential Medicines and Medical Supplies: Policy and Guidance* (2011).

Selection focused on identifying products appropriate for use in the majority of OFDA supported health programs. Every health program should have an EML. This does not mean that all pharmaceuticals should be available at every level of care or that all the products on the OFDA EML are appropriate for every program. Pharmaceuticals requested for OFDA supported health programs are reviewed for appropriateness for the health intervention, the situation, and the country in addition to safety, efficacy, and quality.

Note: because a pharmaceutical is included in the OFDA EML, it does NOT convey blanket approval for use.

OFDA does not traditionally support pharmaceuticals supplied by national programs (e.g., expanded program for immunization; antiretrovirals; reproductive health; antituberculosis) of Ministry of Health in collaboration with WHO, UNICEF, national HIV, and/or Tuberculosis programs. Pharmaceutical support for some of these areas may be appropriate for OFDA programs on a case-by-case justification basis. Where appropriate, OFDA supports partners obtaining their pharmaceutical needs through use of standardized pharmaceutical kits (e.g., UNFPA PEP kit).

The contents of the OFDA EML and its utility will be reviewed on a regular basis and revised as needed.

The following symbols are used throughout the OFDA EML. They are taken from the *WHO Model List* explanatory notes, March 2011.

“The **square box symbol** (□) is primarily intended to indicate similar clinical performance within a pharmacological class. The listed medicine should be the example of the class for which there is the best evidence for effectiveness and safety. In some cases, this may be the first medicine that is licensed for marketing; in other instances, subsequently licensed compounds may be safer or more effective. Where there is no difference in terms of efficacy and safety data, the listed medicines should be the one that is generally available at the lowest price, based on international drug price information sources.”

“The **[c] symbol** is placed next to an individual medicine or strength of medicine it signifies that there is a specific indication for restricting its use to children.” (Basically – if a [c] is used the product is only supposed to be used for children.)

Alphabetical Listing of Pharmaceutical Products

| Product Name | Category Number(s) |
|-------------------------------|------------------------|
| Acetazolamide | 21.4 |
| Acetylsalicylic acid | 2.1; 12.5 |
| Acyclovir | 6.4.1; 21.1 |
| Adrenaline | see Epinephrine |
| Albendazole | 6.1.2 |
| Amiloride | 16 |
| Amiodarone | 12.2 |
| Amlodipine | 12.3 |
| Amodiaquine | 6.5.3.1 |
| Amoxicillin | 6.2.1 |
| Amoxicillin + clavulanic acid | 6.2.1 |
| Amphotericin B | 6.5.2 |
| Ampicillin | 6.2.1 |
| Antitetanus immunoglobulin | 19.2 |
| Artemether | 6.5.3.1 |
| Artemether + lumefantrine | 6.5.3.1 |
| Artesunate | 6.5.3.1 |
| Artesunate + amodiaquine | 6.5.3.1 |
| Ascorbic acid | 27 |
| Atovaquone + proguanil | 6.5.3.2 |
| Atracurium | 20 |
| Atropine | 1.3; 4.2; 21.5 |
| Azithromycin | 6.2.2 |
| Beclomethasone | 25.1 |
| Benzathine benzylpenicillin | 6.2.1 |
| Benznidazole | 6.5.5.2 |
| Benzyl benzoate | 13.5 |
| Benzylpenicillin | 6.2.1 |
| Betamethasone | 13.3 |
| Bisoprolol | 12.1; 12.2; 12.3; 12.4 |
| Budesonide | 25.1 |
| Bupivacaine | 1.2 |
| Calamine | 13.3 |
| Calcium gluconate | 4.2 |
| Carbamazepine | 5; 24.2.2 |
| Cefalexin | 6.2.1 |
| Cefazolin | 6.2.1 |
| Cefixime | 6.2.1 |
| Ceftazidime | 6.2.1 |
| Ceftriaxone | 6.2.1 |
| Charcoal, activated | 4.1 |
| Chloramphenicol | 6.2.2 |
| Chlorhexidine | 15.1 |
| Chlorine base compound | 15.2 |
| Chloroquine | 6.5.3.1; 6.5.3.2 |
| Chloroxylenol | 15.2 |
| Chlorpheniramine | 3 |
| Chlorpromazine | 24.1 |
| Ciprofloxacin | 6.2.2 |

| Product Name | Category Number(s) |
|----------------------------------|-------------------------|
| Clotrimazole | 6.3 |
| Cloxacillin | 6.2.1 |
| Cyclopentolate | See Atropine 21.5 |
| Dexamethasone | 3 |
| Diazepam | 5; 24.3 |
| Diethylcarbamazine | 6.1.2 |
| Digoxin | 12.2; 12.4 |
| Diphtheria vaccine | 19.3 |
| Doxycycline | 6.2.2; 6.5.3.1; 6.5.3.2 |
| Eflornithine | 6.5.5.1 |
| Erythromycin | 6.2.2 |
| Epinephrine | 3; 12.2; 25.1 |
| Enalapril | 12.3; 12.4 |
| Ethanol | 15.1 |
| Ergometrine | 22.1 |
| Ferrous salt | 10.1 |
| Ferrous salt + folic acid | 10.1 |
| Fluconazole | 6.3 |
| Fluorescein | 14.1 |
| Fluoxetine | 24.2.1 |
| Fluphenazine | 24.1 |
| Folic acid | 10.1 |
| Furosemide | 12.4; 16 |
| Gentamicin | 6.2.2; 21.1 |
| Glibenclamide (glyburide) | 18.5 |
| Glucagon | 18.5 |
| Glucose | 26.2 |
| Glucose with sodium chloride | 26.2 |
| Glutaral | 15.2 |
| Glyceryl trinitrate | 12.1 |
| Haloperidol | 24.1 |
| Halothane | 1.1.1 |
| Heparin | 10.2 |
| Homatropine | See Atropine 21.5 |
| Hydralazine | 12.3 |
| Hydrochlorothiazide(HCTZ) | 12.3; 12.4; 16 |
| Hydrocortisone | 3; 13.3 |
| Hydroxocobalamin | 10.1 |
| Ibuprofen | 2.1 |
| Insulin (soluble) | 18.5 |
| Insulin, intermediate acting | 18.5 |
| Ipratropium bromide | 25.1 |
| Isoflurane | 1.1.1 |
| Isosorbide dinitrite | 12.1 |
| Ivermectin | 6.1.2 |
| Ketamine | 1.1.1 |
| Lamivudine (3TC) | 6.4.2.1 |
| Levonorgestrel | 18.3.1 |
| Levothyroxine | 18.8 |

| Product Name | Category Number(s) |
|------------------------------|-------------------------|
| Lidocaine | 1.2; 12.2 |
| Lidocaine + epinephrine | 1.2 |
| Lithium carbonate | 24.2.2 |
| Lorazepam | 5 |
| Magnesium sulfate | 5 |
| Mebendazole | 6.1.1 |
| Mefloquine | 6.5.3.1; 6.5.3.2 |
| Melarsoprol | 6.5.5.1 |
| Metformin | 18.5 |
| Methyldopa | 12.3 |
| Metoclopramide | 17.2 |
| Metronidazole | 6.2.2; 6.5.1 |
| Miconazole | 13.1 |
| Midazolam | 1.3 |
| Miltefosine | 6.5.2 |
| Misoprostol | 22.1 |
| Morphine | 1.3; 2.2 |
| Mupirocin | 13.2 |
| Naloxone | 4.2 |
| Neostigmine | 20 |
| Niclosamide | 6.1.1 |
| Nifedipine | 22.2 |
| Nifurtimox | 6.5.5.1; 6.5.5.2 |
| Nitrofurantoin | 6.2.2 |
| Nitroglycerin | See Glyceryl trinitrate |
| Nitrous oxide | 1.1.1 |
| Nystatin | 6.3 |
| Omeprazole | 17.1 |
| Ondansetron | 17.2 |
| Oral rehydration salts (ORS) | 17.5.1; 26.1 |
| Oxygen | 1.1.1 |
| Oxytocin | 22.1 |
| Paracetamol | 2.1 |
| Paromomycin | 6.5.2 |
| Pentamidine | 6.5.5.1 |
| Permethrin | 13.5 |
| Phenobarbital | 5 |
| Phenoxyethylpenicillin | 6.2.1 |
| Phenytoin | 5 |
| Phytomenadione | 10.2 |
| Pilocarpine | 21.4 |
| Potassium Chloride | 26.1; 26.2 |
| Potassium iodide | 18.8 |
| Potassium permanganate | 13.2 |
| Polyvidone iodine | 15.1 |
| Product Name | Category Number(s) |
| Praziquantel | 6.1.1; 6.1.3 |

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|--------------------------------|------------|
| Prednisolone | 3; 21.2 |
| Primaquine | 6.5.3.1 |
| Procaine benzylpenicillin | 6.2.1 |
| Proguanil | 6.5.3.2 |
| Propofol | 1.1.2 |
| Propylthiouracil | 18.8 |
| Protamine sulfate | 10.2 |
| Pyrantel | 6.1.1 |
| Pyridostigmine | 20 |
| Quinine | 6.5.3.1 |
| Retinol | 27 |
| Salbutamol | 25.1 |
| Selenium sulfide | 13.1 |
| Senna | 17.4 |
| Silver sulfadiazine | 13.2 |
| Simvastatin | 12.6 |
| Sodium chloride | 26.2 |
| Sodium hydrogen carbonate | 26.2 |
| Sodium lactate compd solution | 26.2 |
| Sodium stibogluconate | 6.5.2 |
| Spirolactone | 16 |
| Sulfadoxine+pyrimethamine | 6.5.3.1 |
| Sulfamethoxazole-trimethoprim | 6.2.2 |
| Suramin sodium | 6.5.5.1 |
| Suxamethonium (succ.choline) | 20 |
| Terbinafine | 13.1 |
| Tetanus vaccine | 19.3 |
| Tetracaine | 21.3 |
| Tetracycline | 21.1 |
| Thiopental | 1.1.2 |
| Timolol | 21.4 |
| Tranexamic acid | 10.2 |
| Triclabendazole | 6.1.3 |
| Tropicamide | 14.1 |
| Valproic acid | 5; 24.2.2 |
| Vecuronium | 20 |
| Verapamil | 12.1; 12.2 |
| Warfarin | 10.2 |
| Water for injection | 26.3 |
| Zidovudine (ZDV or ACT) | 6.4.2.1 |
| Zidovudine/lamivudine | 6.4.2.1 |
| Zinc sulfate | 17.5.2 |

***Red bold faced font** – reflects product has a **restricted indication**

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| 1. Anesthetics | |
| 1.1 General anesthetics and oxygen | |
| 1.1.1 Inhalational medicines | |
| Halothane | Inhalation |
| Isoflurane | Inhalation |
| Nitrous oxide | Inhalation |
| Oxygen | Inhalation |
| 1.1.2 Injectable medicines | |
| Ketamine | Injection: 50 mg(as hydrochloride)/ml in 10-ml vial |
| Propofol (or thiopental as alternative) | Injection: 10mg/ml; 20mg/ml |
| 1.2 Local anesthetics | |
| <input type="checkbox"/> Bupivacaine | Injection: 0.25%; 0.5% (hydrochloride) in vial Injection for spinal anesthesia: 0.5% (hydrochloride) in 4-ml ampoule to be mixed with 7.5% glucose solution |
| <input type="checkbox"/> Lidocaine | Injection: 1%; 2% (hydrochloride) in vial Injection for spinal anesthesia: 5% (hydrochloride) in 2-ml ampoule to be mixed with 7.5% glucose solution Topical forms: 2% to 4% (hydrochloride) |
| Lidocaine + epinephrine (adrenaline) | Injection: 1%; 2% (hydrochloride or sulfate) + epinephrine 1:200,000 in vial |
| 1.3 Preoperative medication and sedation for short-term procedures | |
| Atropine | Injection: 1mg (sulfate) in 1-ml ampoule |
| <input type="checkbox"/> Midazolam | Injection: 1mg/ml Oral liquid: 2mg/ml [c] Tablet: 7.5mg; 15mg |
| Morphine | Injection: 10mg (sulfate or hydrochloride) in 1-ml ampoule |
| 2. Analgesics, antipyretics, non-steroidal anti-inflammatory medicines (NSAIDs), medicines used to treat gout and disease modifying agents in rheumatoid disorders (DMARDs) | |
| 2.1 Non-opioids and non-steroidal anti-inflammatory medicines (NSAIDs) | |
| Acetylsalicylic acid | Suppository: 50mg to 150mg Tablet: 100mg to 500mg |
| Ibuprofen | Oral liquid: 200mg/5ml Tablet: 200mg, 400mg Restricted to use in children > 3 months |
| Paracetamol | Oral liquid: 125mg/5ml Suppository: 100mg Tablet: 100mg to 500mg Not to be used as anti-inflammatory |
| 2.2 Opioid analgesics | |
| Morphine | Injection: 10mg (as hydrochloride or sulfate) in 1-ml ampoule Oral liquid: 10mg (hydrochloride or sulfate)/5ml Tablet: 10mg (sulfate) Tablet (prolonged release): 10mg; 30mg; 60mg (sulfate) |

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| 2.3 Medicines to treat gout – [None in OFDA EML] | |
| 2.4 Disease modifying agents used in rheumatoid disorders (DMARDs) – [None in OFDA EML] | |
| 3. Antiallergics and medicines used in anaphylaxis | |
| Chlorpheniramine | Injection: 10mg (hydrogen maleate) in 1-ml ampoule Oral liquid: 2mg/5ml (hydrogen maleate) [c]; > 1 year Tablet: 4mg (hydrogen maleate) |
| Dexamethasone | Injection: 4mg/ml in 1-ml ampoule (as disodium phosphate salt) |
| Epinephrine (adrenaline) | Injection: 1mg (as hydrochloride or hydrogen tartrate) in 1-ml ampoule |
| Hydrocortisone | Powder for injection: 100mg (as sodium succinate) in vial |
| <input type="checkbox"/> Prednisolone | Oral liquid: 5mg/ml [c] Tablet: 5mg; 25mg |
| 4. Antidotes and other substances used in poisonings | |
| 4.1 Non-specific | |
| Charcoal, activated | Powder |
| 4.2 Specific | |
| Atropine | Injection: 1mg (sulfate) in 1-ml ampoule |
| Calcium gluconate | Injection: 100mg/ml in 10-ml ampoule |
| Naloxone | Injection: 400micrograms (hydrochloride) in 1-ml ampoule |
| 5. Anticonvulsants/antiepileptics | |
| Carbamazepine | Oral liquid: 100mg/5ml Tablet (chewable): 100mg; 200mg Tablet (scored): 100mg; 200mg |
| Diazepam | Gel or rectal solution: 5mg/ml in 0.5ml; 2-ml; 4-ml tubes |
| <input type="checkbox"/> Lorazepam | Parenteral formulation: 2mg/ml in 1-ml ampoule; 4mg/ml in 1-ml ampoule |
| Magnesium sulfate (restricted use for eclampsia and severe pre-eclampsia only) | Injection: 500mg/ml in 2-ml ampoule; 500mg/ml in 10-ml ampoule |
| Phenobarbital | Injection: 200mg/ml (sodium) Oral liquid: 15mg/5ml Tablet: 15mg to 100mg |
| Phenytoin | Injection: 50mg/ml in 5-ml vial (sodium salt) Oral liquid: 25mg/5ml or 30mg/5ml (not both) Solid oral dosage form: 25mg; 50mg; 100mg (sodium salt) Tablet (chewable): 50mg |
| Valproic acid (sodium valproate) | Oral liquid: 200mg/5ml Tablet (crushable): 100mg Tablet (enteric-coated): 200mg; 500mg (sodium valproate) |
| 6. Anti-infective medicines | |
| 6.1 Anthelmintic | |
| 6.1.1 Intestinal anthelmintics | |

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| Mebendazole | Tablet (chewable): 100mg, 500mg |
| Niclosamide (only if praziquantel treatment fails) | Tablet (chewable): 500mg |
| Praziquantel | Tablet: 150mg; 600mg |
| Pyrantel | Oral liquid: 50mg (as embonate or pamoate)/ml Tablet (chewable): 250mg (as embonate or pamoate) |
| 6.1.2 Antifilarials | |
| Albendazole | Tablet (chewable): 400mg |
| Diethylcarbamazine | Tablet: 50mg; 100mg (dihydrogen citrate) |
| Ivermectin | Tablet (scored): 3mg; 6mg |
| 6.1.3 Antischistosomes and other antitrematode medicines | |
| Praziquantel | Tablet: 600mg |
| Triclabendazole | Tablet: 250mg |
| 6.2 Antibacterials | |
| 6.2.1 Beta Lactam medicines | |
| Amoxicillin | Powder for oral liquid: 125mg (as trihydrate)/5ml; 250mg (as trihydrate)/5ml [c] Solid oral dosage form: 250mg; 500mg (as trihydrate) |
| Amoxicillin + clavulanic acid | Oral liquid: 125mg amox + 31.25mg clavulanic acid/5ml AND 250mg amox+62.5mg clavulanic acid/5ml [c] Tablet: 500mg (as amox trihydrate) + 125mg (as clavulanic potassium salt) |
| Ampicillin (injection only) | Powder for injection: 500mg; 1 g(as sodium salt) in vial |
| Benzathine benzylpenicillin | Powder for injection: 900mg benzylpenicillin (1.2 million IU) in 5-ml vial [c]; 1.44g benzylpenicillin (2.4 million IU) in 5-ml vial |
| Benzylpenicillin | Powder for injection: 600mg (1 million IU); 3g (5 million IU) (sodium or potassium salt) in vial |
| Cefalexin [c] | Powder for reconstitution with water: 125mg/5ml; 250mg/5ml (anhydrous) Solid oral dosage form: 250mg (as monohydrate) |
| <input type="checkbox"/> Cefazolin – restricted use for surgical prophylaxis | Powder for injection: 1g (as sodium salt) in vial; children must be age > 1month |
| Cefixime – restricted use for single-dose treatment of uncomplicated anogenital gonorrhea | Capsule: 400mg (as trihydrate) |
| Ceftriaxone | Powder for injection: 250mg; 1 g (as sodium salt) in vial; children must be >41 weeks corrected gestational age; do not administer with calcium and avoid in infants with hyperbilirubinemia |
| <input type="checkbox"/> Cloxacillin | Capsule: 500mg; 1g (as sodium salt) Powder for injection: 500mg (as sodium salt) in vial Powder for oral liquid: 125mg (as sodium salt)/5ml |
| Phenoxyethylpenicillin | Powder for oral liquid: 250mg (as potassium salt)/5ml Tablet: 250mg (as potassium salt) |
| Procaine benzylpenicillin | Powder for injection: 1g (1 million IU); 3g (3 million IU) in vial; NOT recommended as 1st-line treatment for neonatal sepsis except in settings with high neonatal mortality, when given by trained health workers in cases where hospital care is not achievable. |
| Ceftazidime | Powder for injection: 250mg or 1g (as pentahydrate) in vial |
| 6.2.2 Other antibacterials | |

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| Azithromycin – restricted use only for single-dose treatment of genital <i>Chlamydia trachomatis</i> and of trachoma | Capsules: 250mg; 500mg (anhydrous) Oral liquid: 200mg/5ml |
| Chloramphenicol | Capsule: 250mg Oily suspension for injection: 0.5g (as sodium succinate)/ml in 2-ml ampoule; only for presumptive treatment of epidemic meningitis in children older than 2 years Oral liquid: 150mg (as palmitate)/5ml Powder for injection: 1g (sodium succinate) in vial |
| <input type="checkbox"/> Ciprofloxacin | Oral liquid: 250mg/5ml (anhydrous) [c] Solution for IV Infusion: 2mg/ml (as hyclate) [c] Tablet: 250mg (as hydrochloride) (<input type="checkbox"/> - applies to adults only) |
| Doxycycline | Oral liquid: 25mg/5ml [c]; 50mg/5ml [c] Solid oral dosage form: 50mg [c]; 100mg (as hyclate) (use in children < 8 years is only for life-threatening infections when no alternative exists) |
| <input type="checkbox"/> Erythromycin | Powder for injection: 500mg (as lactobionate) in vial Powder for oral liquid: 125mg/5ml (as stearate or estolate or ethyl succinate) Solid oral dosage form: 250mg (as stearate or estolate or ethyl succinate) |
| <input type="checkbox"/> Gentamicin | Injection: 10mg; 40mg (as sulfate)/ml in 2-ml vial |
| <input type="checkbox"/> Metronidazole | Injection: 500mg in 100-ml vial Oral liquid: 200mg (as benzoate)/5ml Suppository: 500mg; 1g Tablet: 200mg to 500mg |
| Nitrofurantoin | Oral liquid: 25mg/5ml [c] Tablet: 100mg |
| Sulfamethoxazole + trimethoprim (SMZ/TMP) | Injection: 80mg (SMZ) + 16mg (TMP)/ml in 5ml ampoule; 80mg (SMZ) + 16mg (TMP)/ml in 10ml ampoule Oral liquid: 200mg (SMZ)+40mg(TMP)/5ml Tablet: 100mg (SMZ)+20mg(TMP); 400mg(SMZ)+80mg(TMP); 800mg(SMZ)+160mg(TMP) |
| Clindamycin | Capsule: 150mg (as hydrochloride) Injection: 150mg (as phosphate)/ml Oral liquid: 75mg/5ml (as palmitate) [c] |
| 6.2.3 Antileprosy medicines [None in OFDA EML] | |
| 6.2.4 Antituberculosis medicines [None in OFDA EML] | |
| 6.3 Antifungal medicines | |
| Clotrimazole | Vaginal cream: 1%; 10% Vaginal tablet: 100mg; 500mg |
| <input type="checkbox"/> Fluconazole | Capsule: 50mg Injection: 2mg/ml in vial Oral liquid: 50mg/5ml |
| Nystatin | Lozenge: 100,000 IU Oral liquid: 50mg/5ml [c]; 100,000 IU/ml [c] Pessary: 100,000 IU Tablet: 100,000 IU; 500,000 IU |

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| 6.4 Antiviral medicines | |
| 6.4.1 Antiherpes medicines | |
| <input type="checkbox"/> Acyclovir | Oral liquid: 200mg/5ml [c] Powder for injection: 250mg (as sodium salt) in vial Tablet: 200mg |
| 6.4.2 Antiretrovirals | |
| 6.4.2.1 Nucleoside/Nucleotide reverse transcriptase inhibitors – restricted use as post-exposure prophylaxis (PEP) treatments in accordance with global and national guidelines, following UNFPA PEP kit contents. All ARVs must be US FDA approved or have tentative approval. | |
| Lamivudine (3TC) | Oral liquid: 50mg/5ml Tablet: 150mg |
| Zidovudine (ZDV or AZT) | Capsule: 100mg; 250mg Oral liquid: 50mg/5ml Solution for IV infusion injection: 10mg/ml in 20-ml vial Tablet: 300mg |
| Zidovudine/Lamivudine (AZT/ 3TC) | Tablet: 60mg (AZT)/30mg(3TC) [c]; 300mg(AZT)/150mg(3TC) |
| 6.4.2.2 Non-nucleoside reverse transcriptase inhibitors – [None in OFDA EML] | |
| 6.4.2.3 Protease inhibitors – [None in OFDA EML] | |
| 6.4.3 Other antivirals – [None in OFDA EML] | |
| 6.5 Antiprotozoal medicines | |
| 6.5.1 Antiamoebic and anti giardiasis medicines | |
| <input type="checkbox"/> Metronidazole | Injection: 500mg in 100-ml vial Oral liquid: 200mg (as benzoate)/5ml Tablet: 200mg to 500mg |
| 6.5.2 Antileishmaniasis medicines | |
| Amphotericin B | Powder for injection: 50mg in vial (as sodium deoxycholate or liposomal complex) |
| Miltefosine | Solid oral dosage form: 10mg; 50mg |
| Paromomycin | Solution for intramuscular injection: 750mg (of paromomycin base as the sulfate) |
| Sodium stibogluconate or meglumine antimoniate | Injection: 100mg/ml, 1 vial = 30ml or 30%, equivalent to approximately 8.1% antimony (pentavalent) in 5-ml ampoule |
| 6.5.3 Antimalarial medicines – Specific treatments should be <u>in accordance</u> with global and national treatment <u>guidelines and resistance patterns</u> please note requirements on use of specific products together. Medicines for the treatment of <i>P. falciparum</i> malaria cases should be used in combination. All anti-malarials must meet the following: (1) US FDA or Stringent Regulatory Authority (SRA) approval; or (2) Prequalified by the WHO; or (3) Purchased from a USAID/OFDA pre-qualified pharmaceutical wholesaler <u>AND</u> included in the WHO malaria treatment guidance. | |
| 6.5.3.1 For curative treatment | |
| Amodiaquine – only in combination with artesunate 50 mg | Tablet: 153mg or 200mg (as hydrochloride) |
| Artemether – only for the management of severe malaria | Oily injection: 20mg/ml; and 80mg/ml in 1-ml ampoule |
| Artemether + lumefantrine | Tablet: 20mg +120mg Tablet (dispersible): 20mg + 120mg [c] not recom for 1st trimester of preg or in child <5 kg |

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| Artesunate | Injection: 60mg (as anhydrous artesunic acid) ampoule with separate 5% sodium bicarbonate solution ampoule Rectal dosage form: 50mg [c]; 200mg capsules – restricted to pre-referral treatment of severe malaria only, patients should be taken to appropriate health facility for follow-up care [c] Tablet: 50mg For combo w/either amodiaquine, mefloquine, or sulfadoxine + pyrimethamine |
| Artesunate + Amodiaquine | Tablet: 25mg+67.5mg; 50+135mg; 100mg+270mg (Other combinations that deliver the target doses of amodiaquine required such as 153mg or 200mg (as hydrochloride) with 50 mg artesunate can be alternatives) |
| Chloroquine – restricted use only for the treatment of P.vivax infection where not resistant | Oral liquid: 50mg (as phosphate or sulfate)/5ml Tablet: 100mg; 150mg (as phosphate or sulfate) |
| Doxycycline - in combination with quinine | Capsule: 100mg (as hydrochloride or hyclate) Table t(dispersible): 100mg (as monohydrate) |
| Mefloquine – in combination with artesunate 50mg | Tablet: 250mg (as hydrochloride) |
| Primaquine- only to achieve radical cure of P.vivax and P.ovale infections, given for 14 days) | Tablet: 7.5mg; 15mg (as diphosphate) |
| Quinine- only for management of severe malaria, and in combination with doxycycline, tetracycline, or clindamycin | Injection: 300mg quinine hydrochloride/ml in 2-ml ampoule Tablet: 300mg (sulfate) or 300mg (bisulfate) |
| Sulfadoxine + pyrimethamine - only in combination with artesunate 50 mg | Tablet: 500mg+25mg |
| 6.5.3.2 For prophylaxis – following most current guidelines and resistance patterns for geographic location | |
| Chloroquine – | Oral liquid: 50mg (as phosphate or sulfate)/5ml Tablet: 150mg (as phosphate or sulfate) |
| Doxycycline | Solid oral dosage form: 100mg (as hydrochloride or hycalte); children must be > 8 years |
| Mefloquine | Tablet: 250mg (as hydrochloride); children must be > 5kg or > 3months |
| Proguanil – only in combination with chloroquine | Tablet: 100mg (as hydrochloride) |
| Atovaquone + Proguanil | Tablet: 250mg + 100mg |
| 6.5.4 Antipneumocystosis and antitoxoplasmosis medicines [None in OFDA EML] | |
| 6.5.5 Antitrypanosomal medicines | |
| 6.5.5.1 African trypanosomiasis | |
| Treatment of 1st stage African trypanosomiasis | |
| Pentamidine – only for treatment of <i>Trypanosoma brucei gambiense</i> | Powder for injection: 200mg(as isetionate) in vial |
| Suramin sodium – only for treatment of initial phase of <i>Trypanosoma brucei rhodesiense</i> | Powder for injection: 1 g in vial |
| Treatment of 2nd stage African trypanosomiasis | |
| Eflornithine – treatment of <i>Trypanosoma brucei gambiense</i> | Injection: 200mg (hydrochloride)/ml in 100ml bottle |
| Melarsoprol | Injection: 3.6% solution, 5-ml ampoule (180mg active compound) |
| Nifurtimox – used in combination with eflonithin, for treatment of <i>Trypanosoma brucei gambiense</i> | Tablet: 120mg |

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| | |
|---|---|
| 6.5.5.2 American trypanosomiasis | |
| Benznidazole | Tablet: 100mg |
| Nifurtimox | Tablet: 30mg; 120mg; 250mg |
| 7. Antimigraine medicines [None in OFDA EML] | |
| 8. Antineoplastic, immunosuppressives and medicines used in palliative care [None in OFDA EML] | |
| 9. Antiparkinsonism Medicines [None in OFDA EML] | |
| 10. Medicines affecting the blood | |
| 10.1 Antianemia medicines | |
| Ferrous salt | Oral liquid: equivalent to 25mg iron (as sulfate)/ml Tablet: equivalent to 60mg iron |
| Ferrous salt + folic acid – only for nutritional supplement during pregnancy | Tablet: equivalent to 60mg iron + 400 microgram folic acid |
| Folic acid | Tablet: 1mg; 5mg |
| Hydroxocobalamin | Injection: 1mg (as acetate, hydrochloride or as sulfate) in 1-ml ampoule |
| 10.2 Medicines affecting coagulation | |
| Heparin sodium | Injection: 1000 IU/ml; 5000 IU/ml; 20,000 IU/ml in 1-ml ampoules |
| Phytomenadione | Injection: 1mg/ml [c]; 10mg/ml in 5-ml ampoule Tablet: 10mg |
| Protamine sulfate | Injection: 10mg/ml in 5-ml ampoule |
| Tranexamic acid | Injection: 100mg/ml in 10-ml ampoule |
| Warfarin | Tablet: 1mg; 2mg; 5mg (sodium salt) |
| Other medicines for hemoglobinopathies [None in OFDA EML] | |
| 11. Blood products and plasma substitutes or expanders [None in OFDA EML] | |
| 12. Cardiovascular medicines | |
| 12.1 Antianginal medicines | |
| <input type="checkbox"/> Bisoprolol | Tablet: 1.25mg; 5mg (Includes metoprolol and carvedilol as alternatives) |
| Glyceryl trinitrate | Tablet (sublingual): 500micrograms |
| <input type="checkbox"/> Isosorbide dinitrate | Tablet (sublingual): 5mg |
| Verapamil | Tablet: 40mg; 80mg (hydrochloride) |
| 12.2 Antiarrhythmic medicines | |
| <input type="checkbox"/> Bisoprolol | Tablet: 1.25mg; 5mg (Includes metoprolol and carvedilol as alternatives) |
| Digoxin | Injection: 250micrograms/ml in 2-ml ampoule Oral liquid: 50micrograms/ml Tablet: 62.5micrograms; 250micrograms |
| Epinephrine (adrenaline) | Injection: 100micrograms/ml (as acid tartrate or hydrochloride) in 10-ml ampoule |
| Lidocaine | Injection: 20mg (hydrochloride)/ml in 5-ml ampoule |
| Verapamil | Injection: 2.5mg (hydrochloride)/ml in 2-ml ampoule Tablet: 40mg; 80mg (hydrochloride) |

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|--|---|
| Amiodarone | Injection: 50mg/ml in 3-ml ampoule (hydrochloride) Tablet: 100mg; 200mg; 400mg (hydrochloride) |
| 12.3 Antihypertensive medicines | |
| <input type="checkbox"/> Amlodipine | Tablet: 5mg (as maleate, mesylate, or besylate) |
| <input type="checkbox"/> Bisoprolol | Tablet: 1.25mg; 5mg (Includes metoprolol and carvedilol as alternatives) |
| <input type="checkbox"/> Enalapril | Tablet: 2.5mg; 5mg (as hydrogen maleate) |
| Hydralazine – restricted to use in acute management of severe pregnancy-induced hypertension only | Powder for injection: 20mg (hydrochloride) in ampoule Tablet: 25mg; 50mg (hydrochloride) |
| <input type="checkbox"/> Hydrochlorothiazide | Oral liquid: 50mg/5ml Solid oral dosage form: 12.5mg; 25mg |
| Methyldopa- restricted to use in the management of pregnancy-induced hypertension only | Tablet: 250mg |
| 12.4 Medicines used in heart failure | |
| <input type="checkbox"/> Bisoprolol | Tablet: 1.25mg; 5mg |
| Digoxin | Injection: 250micrograms/ml in 2-ml ampoule Oral liquid: 50micrograms/ml Tablet: 62.5micrograms; 250micrograms |
| <input type="checkbox"/> Enalapril | Tablet: 2.5mg; 5mg (as hydrogen maleate) |
| <input type="checkbox"/> Furosemide | Injection: 10mg/ml in 2-ml ampoule Oral liquid: 20mg/5ml [c] Tablet: 40mg |
| <input type="checkbox"/> Hydrochlorothiazide | Oral liquid: 50mg/5ml Solid oral dosage form: 25mg |
| 12.5 Antithrombotic medicines | |
| Acetylsalicylic acid | Tablet: 100mg |
| 12.6 Lipid-lowering agents | |
| <input type="checkbox"/> Simvastatin – restricted to use in high-risk patients | Tablet: 5mg; 10mg; 20mg; 40mg |
| 13. Dermatological medicines (topical) | |
| 13.1 Antifungal medicines | |
| <input type="checkbox"/> Miconazole | Cream or Ointment: 2% (nitrate) |
| Selenium sulfide | Detergent-based suspension: 2% |
| Terbinafine | Cream or Ointment: 1% (hydrochloride) |
| 13.2 Anti-infective medicines | |
| Mupirocin | Cream: 2% (calcium) |
| Potassium permanganate | Aqueous solution: 1:10,000 |
| Silver sulfadiazine | Cream: 1%; children must be > 2 months |
| 13.3 Anti-inflammatory and antipruritic medicines | |
| <input type="checkbox"/> Betamethasone | Cream or ointment: 0.1% (as valerate); not for use in neonates |
| <input type="checkbox"/> Calamine | Lotion |
| <input type="checkbox"/> Hydrocortisone | Cream or ointment: 1% (acetate); prefer use of hydrocortisone in neonates versus steroid topicals |
| 13.4 Medicines affecting skin differentiation and proliferation [None in OFDA EML] | |
| 13.5 Scabicides and pediculicides | |
| Benzyl benzoate | Lotion: 25%; children must be > 2 years |
| Permethrin | Cream: 5%; Lotion: 1% |
| 14. Diagnostic agents | |

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| | |
|--|---|
| 14.1 Ophthalmic medicines | |
| Fluorescein | Eye drops: 1% (sodium salt) |
| <input type="checkbox"/> Tropicamide | Eye drops: 0.5% |
| 14.2 Radiocontrast media [None in OFDA EML] | |
| 15. Disinfectants and antiseptics | |
| 15.1 Antiseptics | |
| <input type="checkbox"/> Chlorhexidine | Solution: 5% (digluconate); 20% (digluconate) must be diluted prior to cord care; [c] |
| <input type="checkbox"/> Ethanol | Solution: 70% (denatured) |
| <input type="checkbox"/> Polyvidone iodine | Solution: 10% (equivalent to 1% available iodine) |
| 15.2 Disinfectants | |
| <input type="checkbox"/> Chlorine base compound | Powder: 0.1% (free chlorine for solution) |
| <input type="checkbox"/> Chloroxylenol | Solution: 4.8% |
| Glutaral | Solution: 2% |
| 16. Diuretics | |
| Amiloride | Tablet: 5mg (hydrochloride) |
| <input type="checkbox"/> Furosemide | Injection: 10mg/ml in 2-ml ampoule Oral liquid: 20mg/5ml [c] Tablet: 10mg [c]; 20mg [c]; 40mg |
| Hydrochlorothiazide | Solid oral dosage form: 25mg |
| <input type="checkbox"/> Spironolactone | Tablet: 25mg |
| 17. Gastrointestinal medicines | |
| 17.1 Antiulcer medicines | |
| <input type="checkbox"/> Omeprazole | Powder for oral liquid: 20mg; 40mg sachets Solid oral dosage form: 10mg; 20mg; 40mg |
| 17.2 Antiemetic medicines | |
| Metoclopramide | Injection: 5mg (hydrochloride)/ml in 2-ml ampoule Oral liquid: 5mg/5ml [c] Tablet: 10mg (hydrochloride) NOT to be used in neonates |
| Ondansetron | Injection: 2mg base/ml in 2-ml ampoule (as hydrochloride) Oral liquid: 4mg base/5ml Solid oral dosage form: Eq 4mg base; Eq 8mg base; Eq 24mg base children must be > 1 month |
| 17.3 Anti-inflammatory medicines [None in OFDA EML] | |
| 17.4 Laxatives | |
| <input type="checkbox"/> Senna | Tablet: 7.5mg (sennosides) (or traditional dosage forms) |
| 17.5 Medicines used in diarrhea | |
| 17.5.1 Oral rehydration | |

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|---|---|---------|-------|--------|-----------------|----------|------------------|-----------|-----------------|---------|-----------|------------|------------|---------|----------|-----------------|---------|--------------------|---------|------------------------------|-------|
| Oral rehydration salts (ORS) | <p>Powder for dilution: in 200ml; 500ml; and 1L Must be the following composition:</p> <table> <tr><td>Glucose</td><td>75mEq</td></tr> <tr><td>Sodium</td><td>75mEq or mmol/L</td></tr> <tr><td>Chloride</td><td>65 mEq or mmol/L</td></tr> <tr><td>Potassium</td><td>20mEq or mmol/L</td></tr> <tr><td>Citrate</td><td>10 mmol/L</td></tr> <tr><td>Osmolarity</td><td>245 mOsm/L</td></tr> <tr><td>Glucose</td><td>13.5 g/L</td></tr> <tr><td>Sodium chloride</td><td>2.6 g/L</td></tr> <tr><td>Potassium chloride</td><td>1.5 g/L</td></tr> <tr><td>Trisodium citrate dihydrate+</td><td>2.9/L</td></tr> </table> <p>+trisodium citrate dihydrate may be replaced by sodium hydrogen carbonate (sodium bicarbonate) 2.5g/L. However – should only be used when product will be immediately used.</p> | Glucose | 75mEq | 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 |
| Glucose | 75mEq | | | | | | | | | | | | | | | | | | | | |
| 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 | | | | | | | | | | | | | | | | | | | | |
| 17.5.2 Medicines for diarrhea in children | | | | | | | | | | | | | | | | | | | | | |
| Zinc sulfate – adjunct to ORS | Solid oral dosage form: 20mg | | | | | | | | | | | | | | | | | | | | |
| 18. Hormones, other endocrine medicines and contraceptives | | | | | | | | | | | | | | | | | | | | | |
| 18.1 Adrenal hormones and synthetic substitutes [None in OFDA EML] | | | | | | | | | | | | | | | | | | | | | |
| 18.2 Androgens [None in OFDA EML] | | | | | | | | | | | | | | | | | | | | | |
| 18.3 Contraceptives – only for use as part of PEP intervention | | | | | | | | | | | | | | | | | | | | | |
| 18.3.1 Oral hormonal contraceptives | | | | | | | | | | | | | | | | | | | | | |
| Levonorgestrel- restricted use only for PEP treatment in accordance with UNFPA guidelines | Tablet: 750micrograms (pack of two), 1.5mg | | | | | | | | | | | | | | | | | | | | |
| 18.4 Estrogens [None in OFDA EML] | | | | | | | | | | | | | | | | | | | | | |
| 18.5 Insulins and other medicines used for diabetes | | | | | | | | | | | | | | | | | | | | | |
| Glibenclamide (glyburide) | Tablet: 2.5mg; 5mg | | | | | | | | | | | | | | | | | | | | |
| Glucagon | Injection: 1mg/ml | | | | | | | | | | | | | | | | | | | | |
| Insulin (soluble) | Injection: 40 IU/ml in 10-ml vial; 100 IU/ml in 10-ml vial | | | | | | | | | | | | | | | | | | | | |
| Intermediate-acting Insulin | Injection: 40 IU/ml in 10-ml vial; 100 IU/ml in 10-ml vial (as compound insulin zinc suspension or isophane insulin) | | | | | | | | | | | | | | | | | | | | |
| Metformin | Tablet: 500mg (hydrochloride) | | | | | | | | | | | | | | | | | | | | |
| 18.6 Ovulation inducers [None in OFDA EML] | | | | | | | | | | | | | | | | | | | | | |
| 18.7 Progestogens [None in OFDA EML] | | | | | | | | | | | | | | | | | | | | | |
| 18.8 Thyroid hormones and antithyroid medicines | | | | | | | | | | | | | | | | | | | | | |
| Levothyroxine | Tablet: 25micrograms [c]; 50 micrograms; 100 micrograms (sodium salt) | | | | | | | | | | | | | | | | | | | | |
| Potassium iodide | Tablet: 60mg | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Propylthiouracil | Tablet: 50mg | | | | | | | | | | | | | | | | | | | | |
| 19. Immunologicals | | | | | | | | | | | | | | | | | | | | | |
| 19.1 Diagnostic agents [None in OFDA EML] | | | | | | | | | | | | | | | | | | | | | |
| 19.2 Sera and immunoglobulins – all plasma fractions should comply with WHO Requirements for the Collection, Processing and Quality Control of Blood, Blood Components and Plasma Derivatives (Revised 1992). WHO Expert Committee on Biological Standardization. Forty-third report. (WHO Technical Reports Series, No. 840, 1994 annex 2). | | | | | | | | | | | | | | | | | | | | | |
| Antitetanus immunoglobulin (human) | Injection: 500 IU in vial | | | | | | | | | | | | | | | | | | | | |

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| 19.3 Vaccines – All vaccines should comply with the WHO Requirements for Biological Substances. The vaccines included are for use post-injury NOT to replace or meet the needs of a comprehensive immunization program (such as EPI). | |
| Diphtheria vaccine | |
| Tetanus vaccine | |
| 20. Muscle relaxants (peripherally-acting) and cholinesterase inhibitors | |
| <input type="checkbox"/> Atracurium | Injection: 10mg/ml (besylate) |
| Neostigmine | Injection: 500 micrograms in 1-ml; 2.5mg (metilsulfate) in 1-ml ampoule Tablet: 15mg (bromide) |
| Suxamethonium (succinylcholine) | Injection: 50mg (chloride)/ml in 2-ml ampoule Powder for injection (chloride) in vial |
| <input type="checkbox"/> Vecuronium – [c] | Powder for injection: 10mg (bromide) in vial |
| Pyridostigmine | Injection: 1mg in 1-ml ampoule Tablet: 60mg (bromide) |
| 21. Ophthalmological preparations | |
| 21.1 Anti-infective agents | |
| Acyclovir ointment | Ointment: 3% W/W |
| <input type="checkbox"/> Gentamicin | Solution (eye drops): 0.3% (sulfate) |
| <input type="checkbox"/> Tetracycline | Eye ointment: 1% (hydrochloride) |
| 21.2 Anti-inflammatory agents | |
| <input type="checkbox"/> Prednisolone | Solution (eye drops): 0.5% (sodium phosphate) |
| 21.3 Local anesthetics | |
| <input type="checkbox"/> Tetracaine | Solution (eye drops): 0.5% (hydrochloride); not for use in preterm neonates |
| 21.4 Miotics and antiglaucoma medicines | |
| Acetazolamide | Tablet: 250mg |
| <input type="checkbox"/> Pilocarpine | Solution (eye drops): 2%, 4% (hydrochloride or nitrate) |
| <input type="checkbox"/> Timolol | Solution (eye drops): 0.25%; 0.5% (as hydrogen maleate) |
| 21.5 Mydriatics | |
| Atropine Or for use in children – homatropine (hydrobromide) or cyclopentolate (hydrochloride) | Solution (eye drops): 0.1%; 0.5%; 1% (sulfate); children should be > 3 months |
| 22. Oxytocics and antioxytocics | |
| 22.1 Oxytocics | |
| <input type="checkbox"/> Ergometrine | Injection: 200micrograms (hydrogen maleate) in 1-ml ampoule |
| Misoprostol | Tablet: 200 micrograms – restricted for use of incomplete abortion and miscarriage, and for prevention of postpartum hemorrhage where oxytocin is not available or cannot be safely used. Vaginal tablet: 25 micrograms – restricted for use of induction of labor where appropriate facilities are available |
| Oxytocin | Injection: 10 IU in 1-ml |

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|--|--|
| 22.2 Antioxytocics (tocolytics) | |
| Nifedipine | Immediate-release capsule: 10mg |
| 23. Peritoneal Dialysis Solution [None on OFDA EML] | |
| 24. Medicines for Mental and Behavioral Disorders | |
| 24.1 Medicines used in psychotic disorders | |
| <input type="checkbox"/> Chlorpromazine | Injection: 25mg (hydrochloride)/ml in 2-ml ampoule Oral liquid: 25mg (hydrochloride)/5ml Tablet: 100mg (hydrochloride) |
| <input type="checkbox"/> Fluphenazine | Injection: 25mg (decanoate or enantate) in 1-ml ampoule |
| <input type="checkbox"/> Haloperidol | Injection: 5mg in 1-ml ampoule Tablet: 2mg; 5mg |
| 24.2 Medicines used in mood disorders | |
| 24.2.1 Medicines used in depressive disorders | |
| Fluoxetine | Solid oral dosage form: 20mg (as hydrochloride) |
| 24.2.2 Medicines used in bipolar disorders | |
| Carbamazepine | Tablet (scored): 100mg; 200mg |
| Lithium carbonate | Solid oral dosage form: 300mg |
| Valproic acid (sodium valproate) | Tablet (enteric-coated): 200mg; 500mg (sodium valproate) |
| 24.3 Medicines for anxiety disorders – refractory to other (non-pharmacologically based) treatment modalities | |
| <input type="checkbox"/> Diazepam | Tablet (scored): 2mg; 5mg |
| 24.4 Medicines used for obsessive compulsive disorders [None in OFDA EML] | |
| 24.5 Medicines for disorders due to psychoactive substance use [None in OFDA EML] | |
| 25. Medicines Acting on the Respiratory Tract | |
| 25.1 Antiasthmatic and medicines for chronic obstructive pulmonary disease | |
| <input type="checkbox"/> Beclomethasone | Inhalation (aerosol): 50 micrograms (dipropionate) per spray; 100mg micrograms (dipropionate) per spray; CFC free formulations |
| <input type="checkbox"/> Budesonide – [c] | Inhalation (aerosol): 100 micrograms per spray; 200 micrograms per spray |
| Epinephrine (adrenaline) | Injection: 1mg (as hydrochloride or hydrogen tartrate) in 1-ml ampoule |
| Ipratropium bromide | Inhalation (aerosol): 20 micrograms/metered dose |
| <input type="checkbox"/> Salbutamol | Inhalation (aerosol): 100 micrograms (as sulfate) per dose Injection: 50 micrograms (as sulfate)/ml in 5-ml ampoule Metered dose inhaler (aerosol): 100 micrograms (as sulfate) per dose Respirator solution for use in nebulizers: 5mg (as sulfate)/ml |
| 26. Solutions correcting water, electrolyte and acid-base disturbances | |
| 26.1 Oral | |

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|---|--|
| Oral rehydration salts | See Section 17.5.1 |
| Potassium chloride | Powder for Solution |
| 26.2 Parenteral | |
| Glucose | Injectable solution: 5% (isotonic); 10% (hypertonic); 50% (hypertonic) |
| Glucose with sodium chloride | Injectable solution: 4% glucose, 0.18% sodium chloride Injectable solution: 5% glucose, 0.9% sodium chloride; and 5% glucose, 0.45% sodium chloride [c] |
| Potassium chloride | Solution: 11.2% in 20-ml ampoule (1.5mmol/ml) Solution for dilution: 7.5% , (1mmol/ml)[c]; 15%, 2mmol/ml [c] |
| Sodium chloride | Injectable solution: 0.9% isotonic |
| Sodium hydrogen carbonate | Injectable solution: 1.4% isotonic Solution: 8.4% in 10-ml ampoule |
| <input type="checkbox"/> Sodium lactate, compound solution | Injectable solution |
| 26.3 Miscellaneous | |
| Water for injection | 2-ml; 5-ml; 10-ml ampoule |
| 27. Vitamins and Minerals | |
| Ascorbic acid | Tablet: 50mg |
| Retinol | Capsule: 50,000 IU; 100,000 IU; 200,000 IU (as palmitate) Oral oily solution: 100,000 IU (as palmitate)/ml in multidose dispenser Tablet (sugar-coated): 10,000 IU (as palmitate) Water-miscible injection: 100,000 IU (as palmitate) in 2-ml ampoule |
| 28. Ear, Nose and Throat Conditions in Children [None in OFDA EML] | |
| 29. Specific Medicines for Neonatal Care [None in OFDA EML] | |

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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”.



Procedures to Purchase Pharmaceuticals and Medical Commodities (vaccines, ORS, IV Fluids, and medical diagnostic tests)

In order to purchase human or veterinary pharmaceuticals, the following steps must be followed in accordance with the Agency's Automated Directives System 310 (ADS 310).

STEP 1: Provide an itemized list of the pharmaceuticals or other medical commodities requested. The list must include the following information:

- Name of medicine – Generic name.
- Strength (dose)
- Quantity – e.g. 10,000 tablets
- Unit cost – e.g. \$25.00 USD / 1000 tablet bottle
- Extended Cost in USD – e.g. 10 X \$25.00 USD = \$250.00 USD
- Total Cost for all meds in USD
- Name of pharmaceutical wholesaler where the pharmaceuticals will be purchased.

It is imperative that USAID/OFDA receives cost information for any medical supplies or medical equipment to support the program budget. Information that may be provided to USAID/OFDA must include the following:

- Item
- Quantity
- Unit cost
- Extended Cost
- Total Cost for all medical supplies or medical equipment

STEP 2: NGOs should provide assurance that the host government Ministry of Health (or ministry responsible drug regulatory authority) has approved the importation of the proposed medicines and use in country. For instance, pharmaceuticals must be allowed for use in the host country by the Ministry of Health, Ministry of Agriculture or other drug regulatory authority responsible for registering medicines and ensuring a safe drug supply in the host country and ensuring a safe drug supply. If a medicine is not specifically approved for importation into the country or is not registered in the country for use, it may be embargoed in customs and prevented from entering the country which may adversely impact USAID/OFDA programs



USAID/OFDA Proposal Guidelines Pharmaceutical Annex C

Request for Approval to Purchase Pharmaceuticals

The following commodities are USAID/OFDA restricted goods. As such, partners must submit a formal request for approval to purchase any of these commodities:

- Essential medicines – human or veterinary
- Long Lasting Insecticidal Nets (LLINs)
- Oral Rehydrating Salts (ORS).

Please submit your request on your organization's letterhead. The request should not exceed 2 pages. You may use the following template in order to submit your request.

[Insert NGO/organizational letterhead]

Ref: *[name of your NGO/organization]* hereby requests approval to purchase non-US FDA approved essential medicines for our program *[insert program title]* in *[insert country]*.

Dear [USAID/OFDA Disaster Operations Specialist],

Background: *[Include a short statement of what you are attempting to accomplish with this program]*

To ensure sufficient supplies of medications needed to treat *[list the medical conditions that will be treated]*, *[name of NGO/organization]* proposes to use USAID/OFDA funds to purchase essential medicines, from *[insert name and address of wholesaler]*.

[Note: USAID/OFDA has recognized a number of international pharmaceutical wholesalers consistently able to provide safe, effective and quality essential medicines and other medical commodities. Please consult the OFDA Pharmacist to obtain the most current list].

Attached is a list of the essential medicines required for this program. *[You may attach a complete list of the essential medicines needed or use the template (Annex D). Information must include: name of medication, strength / dose, quantity, intended use within the scope of the program, unit cost, extended cost, and total cost. If a WHO-recognized kit is being requested, e.g. an Interagency Emergency Health Kit (IEHK) the contents list does not need to be provided].*

Justification: *[Include the number of people you intend to treat and the diseases for which they will be treated]* "We intend to purchase these medical commodities from *[name of wholesaler, address]* because..." *[Please include an explanation of why this wholesaler was selected, previous history of purchasing medicines through this wholesaler, availability of commodities, etc.]*

[If the pharmaceutical wholesaler is not a USAID/OFDA pre-approved pharmaceutical wholesaler, refer to the instructions for providing supporting documentation to allow evaluation of the wholesaler. Note that this process may require weeks or months depending on the responsiveness of the wholesaler. No funds may be authorized to purchase pharmaceuticals from a non-qualified wholesaler].

[In addition, assure USAID/OFDA that the national Ministry of Health (MoH) or other responsible government body has approved the NGO to import the required essential medicines into the country without imposition of duties, fees, handling charges etc. Generally this may be accomplished through attaching a signed letter on letterhead from the Ministry in the host nation responsible for pharmaceuticals (MoH, Customs, etc.) as a separate annex].

Sincerely,

[Insert Signature and Date]



USAID
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**USAID/OFDA Proposal Guidelines
Pharmaceutical Annex D**

Fillable Spreadsheet for Listing Human and Veterinary Pharmaceuticals

| |
|----------------|
| NGO Name: |
| Program Title: |
| Country: |
| Date: |

| Name of medicine, vaccine or material (generic name) | Strength/ Dosage Form | Intended Use* | Quantity (number of units: bottles, vials etc.) | Unit of Issue (Size of container) | Unit Cost (USD) | Total Cost (USD) |
|--|--------------------------|--|---|-----------------------------------|-----------------|------------------|
| 1. Example: Amoxicillin Capsules | 500 mg / capsule | Treatment of upper respiratory infection | 10 bottles | 1,000 capsules per bottle | \$5.00 | \$50.00 |
| 2. | | | | | \$ | \$ |
| 3. | | | | | \$ | \$ |
| 4. | | | | | \$ | \$ |
| 5. | | | | | \$ | \$ |
| 6. | | | | | \$ | \$ |
| Total | | | | | \$ | \$ |



Request to Use a Non-Pre-Qualified Pharmaceutical Wholesaler

Implementing partners often wish to purchase pharmaceuticals from local sources using USAID/OFDA funds, i.e. non-prequalified pharmaceutical wholesalers. This practice is problematic because the safety, efficacy and quality of the pharmaceuticals from these sources cannot be guaranteed.

Please note: The collection and submission of the information required may add weeks if not months to the approval process, depending on the responsiveness of the wholesaler. No USAID/OFDA funds for the purchase of human or pharmaceuticals may be awarded unless the wholesaler is approved.

It is assumed that the implementing partner will approach USAID/OFDA prior to the submission of a proposal that includes pharmaceuticals to be sourced from a non-pre-qualified pharmaceutical wholesaler.

1. **In order to approve a non-pre-qualified pharmaceutical wholesaler – the following information must be provided:** English language translations of all documents submitted:
 - a. Complete address and contact information.
 - b. Website if available.
 - c. Product catalog and price list
 - d. Organizational chart
 - List of principles and their titles.
 - e. Government documents authorizing the sale of pharmaceuticals
 - Current license / permit.
 - f. Quality assurance program SOPs
 - Identify individuals responsible for quality assurance of pharmaceuticals
 - g. Explanation of how products are selected for sale.
 - h. Is the wholesaler able to provide computerized invoices, packing lists with batch numbers and delivery notices?
 - i. Is the wholesaler able to provide Certificates of Analysis for each batch of each medicine sold?
 - j. Does the expiration policy allow a minimum of 12 months dating prior to expiration for all pharmaceuticals sold?
 - k. Photographs of:
 - Exterior of warehouse
 - Signage
 - Delivery dock
 - Shipping dock
 - Storage areas
 - Windows
 - Cold storage
 - Temperature monitors
 - Shelving systems
 - Pest control



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USAID/OFDA Proposal Guidelines Pharmaceutical Annex F

Request for Approval to Purchase Veterinary Pharmaceuticals

Veterinary pharmaceuticals and vaccines (e.g., bacterins, vaccines, serum and anti-serum) are USAID/OFDA restricted goods. As such, partners must submit a formal request (on NGO letterhead in two pages or less) for approval to purchase any of these commodities with OFDA funds. The letter must include the following information:

1. Name of the country and title of the program where the veterinary commodities will be used.
2. The reason for the use of veterinary commodities in the program, approximate numbers, species and animal disease / conditions that will be treated.
3. Name and complete address of the intended supplier and rationale for the selection of this supplier. **NOTE:** The NGO must accept responsibility for the quality, efficacy and safety of products from the supplier.

The following must be included with the letter requesting approval and must be in English:

- Spreadsheet listing the name of each essential veterinary pharmaceutical, including: intended use; strength / dose; quantity; unit cost; extended cost (in USD) and total cost (in USD) [Please see "Pharmaceuticals Annex D" for a template that can be used]
- Documentation that the proposed supplier is licensed to sell veterinary pharmaceuticals and biologicals in the country where the program is being implemented.
- Documentation from the supplier on letterhead stationary that all veterinary medications meet international standards for quality, safety and efficacy, and that all medications have a minimum of 12 months expiration period from the time they are received by the program.
- Documentation from the authorized government ministry that the NGO is allowed to bring these medications into the country without imposition of duties, fees, handling charges, etc. Generally this may be accomplished through a signed letter on letterhead from the Ministry in the host nation responsible for pharmaceuticals (MoH, Customs, etc.).]



USAID/OFDA Prequalified Pharmaceutical Wholesalers

January 2014

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

These wholesalers are listed in alphabetical order and no endorsement is made of any particular wholesaler.

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. **UNICEF, Denmark** www.unicef.org

Please note: The following commodities are USAID/OFDA restricted goods. As such, partners must submit a formal request for approval to purchase any of these commodities.

1. Essential medicines – human or veterinary
2. Long Lasting Insecticidal Nets (LLINs)
3. Oral Rehydrating Salts (ORS)
4. Rapid Field Diagnostic Tests