



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

JAN 08 2020

ADMINISTRATIVE ORDER

No. ~~2019~~ 2020 - 0001

SUBJECT: Guidelines in the Importation, Facilitation and Management of Foreign Donations involving Health and Health-Related Products

I. RATIONALE

The Department of Health (DOH) facilitates the requests for, acceptance of, and distribution of all foreign donations to the health sector following Administrative Order (AO) 2016-0004, dated February 24, 2016, entitled "Revised Guidelines in the Facilitation and Management of Foreign Donations Involving Health and Health-related Products." The said issuance repealed the previous AO 54-A s. 2003, entitled "Guidelines on the Processing and Clearance of Importations through the DOH;" thus, shifting the paradigm from a donor-driven system of accepting foreign donations towards a health system needs based approach.

However, pertinent laws have been passed and the relevant guidelines have been issued subsequent to the issuance of AO 2016-0004, such as Republic Act (RA) No. 10747, otherwise known as the "Rare Disease Act of the Philippines," RA No. 10863, otherwise known as the "Customs Modernization and Tariff Act (CMTA)," RA No. 10963, otherwise known as the "Tax Reform for Acceleration and Inclusion (TRAIN) Law," and RA No. 11223, otherwise known as the "Universal Health Care Act," to name a few. Moreover, with the accession of the Philippines as a Party to the Apostille Convention beginning May 14, 2019, processes for documentary requirements needing authentication are streamlined, thereby necessitating revisions in the current AO.

This new guideline in the importation, facilitation and management of foreign donations involving health and health-related products is necessary in order to align with relevant provisions of the above-mentioned issued laws, rules and regulation.

II. OBJECTIVES

General Objective:

This policy aims to enhance the systems and mechanisms involved in the importation, facilitation and management of foreign donations involving health and health-related products.

Specific Objectives:

1. Update and align the DOH guidelines on foreign donations with current relevant laws and issuances;
2. Establish an efficient and effective monitoring and evaluation system for foreign donations;

3. Create a Technical Working Group on Foreign Donations (TWG-FD) involving health and health-related products; and
4. Identify and update the roles and responsibilities of different DOH Bureaus/Offices, and institutions involved in the facilitation of foreign donations.

III. SCOPE AND COVERAGE

This AO shall apply to all individuals, organizations and institutions, both public and private, and all levels of government engaged in the importation, facilitation and management of all regular donations of foreign origin covering all health and health-related products **during non-emergency situations**. All official donations from foreign governments and diplomatic entities like Official Development Assistance and Foreign Assisted Projects (grant or loan), shall be governed by relevant existing laws, rules and regulations.

Health products shall cover drugs, devices, food, food supplements, cosmetics, toys and childcare articles, household urban hazardous substances as defined in RA No. 9711, otherwise known as the "Food and Drug Administration (FDA) Act of 2009" and enumerated in **Annex A**. Likewise, health-related products shall include all products related to healthcare delivery such as, but not limited to, ambulances, mobile clinics, pre-fabricated health facility structures, and water filtration devices.

In times of emergencies and disasters, DOH AO 2007-0017 entitled, "Guidelines on the Acceptance and Processing of Foreign and Local Donations during Emergency and Disaster Situations," and/or other relevant existing guidelines shall apply.

IV. DEFINITION OF TERMS

1. **Affidavit/Deed of Undertaking** – refers to a written declaration made under oath before a notary public or other authorized person, consisting of a statement of facts made by the party concerned on its responsibilities on the utilization and disposal, as well as the monitoring and reporting of any adverse effect related to the foreign donation. It shall also include a statement that the foreign donation is not intended for sale or commercial use.
2. **Air Waybill** –refers to a transport document for airfreight, used by airlines and international freight forwarders, which specify the holder or consignee of the bill who has the right to claim delivery of the goods when they arrive at the port of destination. It is a contract of carriage that includes carrier conditions, such as limits of liability and claims procedures. In addition, it contains transport instructions to airlines and carriers, a description of the goods, and applicable transportation charges.
3. **Apostille** – refers to the name for a specialized certificate, issued by the Secretary of State. The Apostille is attached to the original document to verify it is legitimate and authentic so it will be accepted in one of the other countries who are members of the Hague Apostille Convention.
4. **Automatic Appropriation** – refers to the one-time legislative authorization to provide funds for a specified purpose, for which the amount may or may not be fixed

by law, and is made automatically available and set aside as needed. Since it is already covered by a separate law, it does not require periodic action by the Congress of the Philippines, and need not be included in the legislation of annual appropriations.

5. **Bill of Lading** – refers to a transport document issued by shipping lines, carriers and international freight forwarders or non-vessel operating common carrier for water-borne freight. The holder or consignee of the bill has the right to claim delivery of the goods at the port of destination. It is a contract of carriage that includes carrier conditions, such as limits of liability and claims procedures. In addition, it contains transport instructions to shipping lines and carriers, a description of the goods, and applicable transportation charges.
6. **Certificate of Free Sale** – refers to a certificate indicating that the goods are normally sold in the open market and approved by the regulatory authority in the country of origin.
7. **Certificate of Pharmaceutical Product** – refers to a certificate in the format recommended by the World Health Organization (WHO), which establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country.
8. **Customs duty** - refers to duty/duties imposed on the importation of goods pursuant to the CMTA.
9. **Deed of Acceptance** – refers to a duly notarized document signed by the recipient/consignee formally accepting the donation.
10. **Deed of Donation** – refers to a duly authenticated or apostillized document, which when delivered gratuitously transfers ownership and interests in property to persons and/or entities.
11. **Official Donation** – refers to aid or donation to the Government of the Philippines (GOP) and considered as an official development assistance (ODA), which is provided bilaterally, from donor to recipient, or channeled through a multilateral development agency such as the United Nations, the World Bank and the like.
12. **Orphan Drug** – refers to any drug or medicine used to treat or alleviate the symptoms of persons afflicted with a rare disease and declared as such, by the DOH upon recommendation of the National Institutes of Health (NIH).
13. **Orphan Product** – refers to any healthcare or nutritional product, other than a drug or medicine, including but not limited to, medical food, diagnostic kits, medical devices and biological products, used to prevent, diagnose, or treat rare diseases and declared as such by the DOH upon the recommendation of the NIH.
14. **Packing List** – refers to a shipping document that contains the quantity and kinds of packages, their contents, the net and gross weight in kilograms, the full dimension and size of each package. It supplements the commercial invoice when numerous items are being shipped or when the quantity, weight or content of articles in a shipment vary.

15. **Pro Forma Invoice** – refers to a draft invoice given by the shipper/donor to a recipient/consignee prior to the shipment of goods. It provides information on the nature, quantity, value and weight of goods to be donated.
16. **Regular Donation** – refers to all other aid or donation that is not considered as ODA and does not pass through the processes of the National Economic Development Authority.

V. GENERAL GUIDELINES

1. All donations shall be based on the following four core principles, as stipulated in the WHO 2010 Guidelines on Foreign Donations:
 - a. Maximum benefit to the recipient
 - b. Respect for wishes and authority of the recipient
 - c. No double standards in quality
 - d. Effective communication between donor and recipients
2. All foreign and foreign-based Filipino donors shall abide by the existing laws, rules and regulations of the Philippines.
3. All donations shall be based on the actual expressed needs of recipients, rather than being donor-driven and shall have target recipients and/or distribution list. All donations shall be based on the strategic plans/development cooperation agenda/local investment plans/work and financial plan of the DOH, local government units (LGUs), other government agencies and civil society and non-government organizations.
4. All donations consigned to the DOH shall be aligned with its current thrusts and programs and shall only be accepted if they are **not** being procured by the DOH.
5. All donations shall *preferably* be brand new and compliant to applicable Philippine standards.
6. All donations shall require clearance from the DOH, FDA and other relevant agencies **prior** to shipment.
7. All donations that are not cleared by the DOH and the FDA based on the existing guidelines shall be pulled out by the donor. The DOH and the FDA shall not be held liable or responsible for any expenses to be incurred in returning or shipping back disapproved donations.
8. All donations are subject to customs duties and taxes, except otherwise provided in any existing laws, rules and regulations. A clear, explicit consignment arrangement on who will shoulder duties and taxes and all other costs to be incurred like brokerage, storage fees and demurrages shall be established before shipment is made.
9. All donations' total costs for payment of customs duties and taxes shall not be greater than the total valued cost of procurement if purchased locally.
10. All donations shall be posted in the DOH website for accountability and transparency purposes.

VI. SPECIFIC GUIDELINES

A. CATEGORIES OF FOREIGN DONATIONS

The DOH shall classify foreign donations into the following types/categories based on the purpose of the donation, as well as the identified payor of importation costs. The types and categories of foreign donations are as follows:

1. Foreign Donations Not Consigned to the DOH

Recipients/consignees of the donations may include private institutions, non-government organizations (NGOs), LGU facilities and non-DOH health facilities. All taxes, fees or duties shall be paid either by the donor or the recipient. In case donations have been directly requested by the LGU or any other agencies/institutions, such donations shall be directly consigned to the requesting party and shall be subject to customs duties, taxes and related charges.

2. Foreign Donations Consigned to the DOH

For donations consigned to the DOH as approved by the Secretary of Health, on a per shipment basis, customs duties and import taxes per RA No. 10863, shall be charged to the DOH through automatic appropriation. There are two subtypes in this category:

a. DOH Consigned and Managed Foreign Donations

These are donations intended for the DOH, its attached agencies, retained hospitals, sanatoria and drug treatment and rehabilitation centers. The DOH shall facilitate the donations' clearance, release, distribution and delivery through its official broker.

b. DOH Consigned but non-DOH Managed Foreign Donations

These are donations intended for non-DOH institutions like LGUs, other government agencies, NGOs and non-profit health facilities but are consigned to the DOH under special circumstances, such as, but not limited to, those identified in Section VI.B.3.d, hereof. The other fees and charges such as brokerage, storage, handling, demurrage, etc., shall be paid either by the donor or recipient/consignee. The recipient/consignee shall be responsible for the management of the donation.

3. Foreign Donation Accompanying Foreign and Surgical Medical Missions

These are donations to be utilized by DOH-cleared foreign surgical and medical missions. The importation costs of these items shall be paid by either the missionaries or the local beneficiaries, depending on the agreement between the two parties.

B. CRITERIA FOR FOREIGN DONATIONS

1. The DOH may accept the following goods and items as donations, as specified in Section III of this AO:
 - a. Health products such as drugs, devices, food, food supplements, cosmetics, toys and childcare articles, household urban hazardous substances as defined in RA No. 9711 and enumerated in **Annex A**.
 - b. Health-related products such as, but not limited to ambulances, mobile clinics, pre-fabricated health facility structures, water filtration devices and other related products, and others as maybe requested by the DOH
2. The donations shall fulfill the criteria on the acceptance of foreign donations as specified in **Annex B**.
3. The following are deemed **NOT** acceptable for donations:
 - a. Expired and adulterated products
 - b. Products with expiration date below 12 months from the expected date of arrival in the country. However, due consideration may be given, provided that the following conditions are met:
 - i. Recipient shall submit the list of identified patients needing the donated pharmaceutical product and the name/s of the physician/s who shall administer the dispensing of the pharmaceutical product;
 - ii. Recipient shall submit a Statement under oath that the pharmaceutical product shall be consumed before the expiry date and the DOH/FDA shall not be held liable for any adverse events that may occur;
 - iii. Recipient shall be responsible for the disposal of the unused products, in accordance with FDA rules and regulations; and
 - iv. For Pharmaceutical products with a total shelf-life of less than two (2) years, at least one third of the shelf-life should remain, with a minimum of six (6) months.
 - c. Products with literature without English translation
 - d. Pharmaceutical products or their generic equivalents that are **not** approved for use in the Philippines and **not** included in the latest edition of the Philippine National Formulary (PNF) nor in the National Standard Treatment Guidelines. However, due consideration to the following may be given, subject to the approval of relevant agencies such as the DOH and the Dangerous Drugs Board:
 - i. Pharmaceutical products not listed in the current edition of the PNF but duly registered in other countries but not in the Philippines, and needed for treatment by a patient;
 - ii. Pharmaceutical products which are FDA registered but not available, or without any available drug substitute, and specifically requested and justified by the recipient;
 - iii. Orphan drugs and orphan products; and
 - iv. Other critically needed drugs, as justified

In such cases, there shall be an agreement between the donor and the recipient. The donor shall inform the recipients of the regulatory status (in the Philippines) of the products to be donated.

- e. Incompletely labeled pharmaceutical products or those **not** bearing the following labeling information: International Nonproprietary Name (INN) or generic name, batch or lot number, dosage form, strength, name of

- manufacturer, country of manufacture, quantity in the container, storage conditions and expiry date
- f. Drugs under the annex list of RA No. 9165, otherwise known as "Comprehensive Dangerous Drugs Act of 2002"
 - g. Experimental/investigational drugs and drugs containing active ingredient/s not found in any currently registered pharmaceutical products
 - h. Food supplements containing herbs and other dietary substances of botanical, animal, artificial, of natural origin with the exemption of vitamins, minerals and amino acid supplements
 - i. Donations, sponsorship, partnership or any favor from tobacco and alcohol industry
 - j. Infant formula, breast milk substitutes, milk supplements, feeding bottles and infant teethingers
 - k. Processed food products that may require special storage conditions such as freezing or chilling (e.g. ice cream, frozen vegetables, dough, etc.)
 - l. Processed meat products from countries with reported cases of pathogenic infections (e.g. African Swine Fever and/or avian virus)

C. REQUIREMENTS

1. The requirements shall depend on the category of the donations as stated under Section VI.A., hereof.
2. The documentary requirements as stated in **Annex C** shall be submitted to the DOH Bureau of International Health Cooperation (BIHC).

D. PROCESS OF IMPORTATION, FACILITATION AND MANAGEMENT OF FOREIGN DONATIONS

1. The processes involved in the importation, facilitation and management of foreign donations shall depend on the category as stated under Section VI.A. For non-DOH consigned donations, the process is shown in **Annex D-1** while the process for DOH consigned donations is shown in **Annex D-2**.
2. Offers of foreign donations shall be processed on a per shipment basis.
3. The Letter of Intent for all donations shall be submitted to the DOH-BIHC at least three (3) months prior to planned shipment from the country of origin to the Philippine port of entry.
4. Proper clearances and approval of the donation shall be obtained from relevant agencies **prior** to shipment
5. All foreign donations shall be subjected to FDA routine inspection.
6. All required documents shall be submitted prior to the release of any foreign donation to the intended recipients. In cases of undeclared goods upon inspection, the donor shall be meted with a corresponding penalty based on relevant existing laws, rules and regulations.
7. The TWG-FD shall ensure the smooth flow of the processes involved in the importation, facilitation and management of foreign donations of health and health-related products.
8. All donors/recipients shall be required to submit a post donation report (PDR), thirty (30) days after the turn-over to the recipient/s. Subsequent requests shall not be processed without submission of PDR.

E. TECHNICAL WORKING GROUP ON FOREIGN DONATION

The TWG-FD shall meet regularly and as necessary to ensure the smooth flow of facilitation and management of foreign donations involving health and health related products to the health sector, in accordance with this AO.

1. The TWG shall be composed of the following:
 - a. Bureau of International Health Cooperation (Convenor)
 - b. Health Facilities and Service Regulatory Bureau
 - c. Health Facility Development Bureau
 - d. Financial Management Service
 - e. Legal Service
 - f. Supply Chain Management Service
 - g. Pharmaceutical Division
2. The TWG shall perform the following functions:
 - a. Deliberate and evaluate foreign donations requesting for DOH consignment in terms of need, compliance to set criteria, cost benefit, availability of warehouse space, etc.
 - b. Identify gaps and challenges, and recommend action on pressing issues related to importation, facilitation and management of foreign donations involving health and health related products.
 - c. Provide recommendations to the Secretary of Health and/or his representative on approval/disapproval of request for DOH consignment
 - d. Develop a Positive List and criteria when an FD will be accepted by DOH
 - e. Participate in the monitoring visits on FD, as necessary.

VII. ROLES AND RESPONSIBILITIES

1. **DONOR** shall
 - a. Coordinate with recipients/consignee to inform them of the donation and to make the necessary arrangements for the processing, release and turn-over of the donation
 - b. Comply with the process/procedures of facilitation and management of foreign donations referred to in **Annex C**
 - c. Ensure the submission of all relevant documentary requirements
 - d. Coordinate with the Philippine Embassy/Consulate to initiate the donation process and apostille the Deed of Donation and other documents to be used in the Philippines, except in countries and territories which are not Apostille-contracting parties, such as Austria, Finland, Germany and Greece, in which the previous process of authentication applies
 - e. Together with the recipient/consignee, assume full responsibility for the payment of customs duties and taxes, fees, and other charges (i.e. brokerage fees, storage fees, etc.) relative to the donation, except if consigned to and managed by the DOH
2. **RECIPIENT/CONSIGNEE** shall
 - a. Comply with the process/procedures of facilitation and management of foreign donations referred in **Annex C**
 - b. Ensure the submission of all relevant documentary requirements

- c. In coordination with the donor, submit to BIHC a Letter of Concurrence/Acceptance of the foreign donation and subsequently, a duly notarized Deed of Acceptance as a documentary requirement
- d. Together with the donor, assume full responsibility for the payment of customs duties and taxes, fees, and other charges (i.e. brokerage fees, storage fees etc.)
- e. Identify a designated or authorized broker and execute an Affidavit/Deed of Undertaking for DOH consigned but non-DOH managed foreign donations
- f. Submit to BIHC, copy furnished the Center for Health Development, within 30 days after the turn-over and/or issuance of Invoice/Delivery Receipt, a Post-Donation Report duly signed by the receiving authority referred to in **Annex E**

3. BUREAU OF INTERNATIONAL HEALTH COOPERATION shall

- a. Act as the over-all coordinator for the facilitation and management of foreign donations, and Convenor/Secretariat of the TWG
- b. Ensure that the donations are aligned with the DOH's thrusts and program strategies
- c. Review and evaluate the documents/request against the criteria stipulated in Section VI.B including the completeness and authenticity of submitted documents
- d. Ensure proper coordination with, and endorsement to relevant offices/agencies for the efficient facilitation of donations
- e. Notify and coordinate with donors regarding clearances, requirements and status of offers of foreign donations
- f. Establish, maintain and update database of all foreign donations for monitoring and reporting purposes
- g. Conduct regular monitoring visits to recipient facilities and institutions
- h. Ensure the adequate dissemination of the AO to relevant organizations and other interested parties
- i. Initiate the review and updating of guidelines, as necessary

4. FOOD AND DRUG ADMINISTRATION shall

- a. Review and evaluate requests for clearance of foreign donations of health products as defined in RA No. 9711
- b. Approve/disapprove requests for clearance necessary for the release of the foreign donations
- c. Conduct physical inspection and collect samples for FDA analysis when necessary
- d. Act as resource person during TWG meeting if the need arises
- e. Issue a Certificate of Product Registration to an applicant company who has filed an application, after due evaluation, prior to shipment for DOH consigned

5. FINANCIAL AND MANAGEMENT SERVICE shall

- a. Act as a member of the TWG for the evaluation of proposed DOH consigned foreign donation
- b. Submit Special Allotment Release Order request to the DBM for the automatic appropriation and charging of customs duties and import taxes of DOH consigned donations
- c. Ensure proper accounting and reporting of donations as required by government accounting and auditing rules and regulations
- d. Submit regular report on utilization of brokerage fees and charging of duties and taxes against automatic appropriation

6. **HEALTH FACILITIES AND SERVICES REGULATORY BUREAU** shall
 - a. Act as a member of the TWG for the evaluation of proposed DOH consigned foreign donations
 - b. Validate the list of equipment needed by the DOH recipient facilities based on the set standards for hospitals
7. **HEALTH FACILITY DEVELOPMENT BUREAU** shall
 - a. Act as a member of the TWG for the evaluation of proposed DOH consigned foreign donation
 - b. Provide recommendations relative to the requests for medical equipment and devices of the health facilities using the Health Facility Enhancement Program of the DOH as basis
8. **LEGAL SERVICE** shall
 - a. Act as a member of the TWG for the evaluation of proposed consigned foreign donations
 - b. Provide legal advice to the TWG as may be necessary
9. **PHARMACEUTICAL DIVISION** shall
 - a. Act as a member of the TWG for the evaluation of proposed DOH consigned foreign donations
 - b. Review list of medicines intended for foreign donations based on existing guidelines
10. **SUPPLY CHAIN MANAGEMENT SERVICE** shall
 - a. Act as the member of the TWG for the evaluation of proposed DOH consigned foreign donations
 - b. Coordinate with and regularly update the BIHC regarding the status of all DOH consigned donations
 - c. Coordinate with relevant agencies to facilitate the clearance and release of all foreign donations consigned to DOH
 - d. For deferred payment of duties and taxes, prepare the Deed of Undertaking to ensure timely release and turnover of donations consigned to and managed by DOH
 - e. For DOH consigned but non-DOH managed foreign donations, coordinate with the identified broker of the donor or recipient regarding the DOH payment of customs duties and import taxes, the release of the shipment and issuance of Delivery Receipt by the broker
 - f. Prepare voucher and facilitate payment of duties and taxes of the foreign donations
 - g. Prepare the Property Transfer Receipts for the distribution/turnover of the foreign donations to recipients

VIII. SEPARABILITY CLAUSE


In the event that any provision or part of this Order is declared unauthorized or rendered invalid by any Court of law, those provisions not affected by such declaration shall remain valid and effective.

IX. REPEALING CLAUSE

This Administrative Order repeals AO No. 2016-0004 dated February 24, 2016 and all other related issuances which are inconsistent with the provisions of this Order.

X. EFFECTIVITY DATE

This Administrative Order shall take effect after fifteen (15) days following the completion of its publication in two (2) newspapers of general circulation and upon filing of three (3) certified copies with the Office of the National Register, UP Law Center.


FRANCISCO T. DUQUE III, MD, MSc.
Secretary of Health

**ANNEX A. DEFINITION OF HEALTH PRODUCTS AS PROVIDED IN RA NO. 9711
OTHERWISE KNOWN AS THE FOOD AND DRUG ADMINISTRATION
(FDA) ACT OF 2009**

1. **Cosmetics** – Any substance or preparation intended to be placed in contact with the external parts of the human body or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly for cleaning them, perfuming them, changing their appearance, and/or correcting body odors and/or protecting or keeping them in good condition.
2. **Devices** – refers to medical devices, radiation and health-related devices.
3. **Drug** – means: (1) articles recognized in official pharmacopeias and formularies, including official homeopathic pharmacopeias, or any documentary supplement to any of them, which are recognized and adopted by the FDA; (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; (3) articles (other than food) intended to affect the structure of any function of the body of humans or animals; or (4) articles intended for use as a component of any articles specified in clauses (1), (2), or (3) but do not include devices or their components, parts or accessories.
4. **Food** – means any processed substance which is intended for human consumption and includes drink for man, beverages, chewing gum and any substances which have been used as an ingredient in the manufacture, preparation or treatment of food.
5. **Food supplement** – means any product intended to supplement the diet that bears or contains one or more of the following ingredients: vitamins, minerals, amino acid, herbs or other dietary substances of botanical, animal, artificial, or natural origin. It is usually in the form of capsules, tablets, liquid, gels, powder or pills and it not presented for use as conventional or as a sole item for a meal or diet, or replacement for drugs or medicines.
6. **Household/urban hazardous substances** – any substance or mixture of substances intended for individual or limited purposes and which is toxic, corrosive, an irritant, a strong sensitizer, is flammable or combustible, or generates pressure through decomposition, heat or other means, if such substance or mixture of substances may cause substantial injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable ingestion by children, but shall not include agricultural fertilizers, agricultural pesticides, and agricultural insecticides and other economic poisons, radioactive substances, or substances intended for use as fuels, coolants, refrigerants and the like.
7. **Health-related products** – are products other than prescription items that, according to the manufacturer or distributor, benefit health.
8. **Medicine** – is the science and practice of establishing, the diagnosis, prognosis, treatment, and prevention of disease; any substance or substances used in treating disease or illness; medicament; remedy.
9. **Pharmaceutical products** – shall include drugs and medicine duly registered with FDA
10. **Toys and Childcare Articles** – any toy or other articles intended for use by children which the FDA may determine to pose an electrical, chemical, physical, or thermal hazard.

ANNEX B. CRITERIA ON THE ACCEPTANCE OF FOREIGN DONATIONS

I. Health Products

1. Pharmaceutical Products

- a. Shall be of good quality
- b. Shall be in good condition, not adulterated nor misbranded
- c. Shall be included in the latest edition of PNF except for products listed in Section VI.B.3
- d. Shall have an expiration date not less than 12 months from the expected time of arrival in the country, except for products stated in Section VI.B.3 which shall be given due consideration
- e. Shall be properly labeled in original packing
- f. Literatures and texts shall be in English or shall have English translation (i.e. label information; name of product; generic name or brand name; name and address of manufacturer; formulation; lot or batch number and expiry date; dosage form and strength)
- g. Shall have Certificate of Pharmaceutical Product (COPP)/Certificate of Free Sale (CFS) by a regulatory body from the country of origin

2. Devices

- a. Shall meet standards promulgated by international bodies, such as ISO Certification
- b. Shall be brand new if consigned to the DOH; if not consigned, preferably brand new and if second hand must be certified to be in good operating/functional condition and the model is not more than two (2) years old
- c. Shall have a CFS issued by a regulatory body from the country of origin
- d. Shall have warranty card applicable in the Philippines, if brand new
- e. Shall be accompanied by Invoice Receipt (from original composition) or Manufacturers Certificate
- f. Shall have a local after-sales service provider, with spare parts, accessories and consumables that are locally available and affordable
- g. Shall be accompanied by provision of training for the end-users, as necessary
- h. Shall have a complete operation manual/brochure written in English or with English translation
- i. Power supply shall conform with Philippine national standards (220/240volts, 60hertz)
- j. Shall be mercury-free
- k. Shall be chlorofluorocarbon (CFC) free
- l. Shelf life of sterile devices shall be at least 12 months upon turn over

3. Processed Food and Food Products

- a. Shall have a minimum of six (6) months expiration date upon arrival in the port of entry
- b. Shall be properly labeled on its original packaging or container, with corresponding English translation of mandatory label information in foreign language with the following minimum information (product name, ingredients list; lot code and expiry/expiration date/use by date/consume before date: and country of origin.
- c. Shall not be adulterated as defined in RA 10611 otherwise known as the "Food Safety Act of 2013"
- d. Packaging shall **not** be damaged, punctured or seals broken or dented for hermetically sealed containers (Tetrapack, canned food). There shall be no signs of leaks and stains on the labels and packaging

- e. Shall have a CFS, Certificate of Quality /Analysis duly authenticated (or Apostillized, if applicable) from the country of origin

3. Cosmetics

- a. Only bath soap, shampoo, conditioner, toothpaste are allowed to be donated.
- b. Shall be properly labeled in original packaging written in English or with English translation with the following minimum information:
 - full ingredient list,
 - manufacturing date,
 - batch or lot number

4. Toys and Childcare Articles

- a. Toys shall be compliant to PNS-BHDT ISO 8124 or its accepted equivalent Parts 1-3 and Phthalates test (if applicable), and to applicable labeling requirements such as age grading, cautionary statements/warnings, instructional literature, and item/model number or SKU.
- b. Childcare Articles shall be compliant to PNS-BHDT ISO 8124 or its accepted equivalent Part 3 and Phthalates test, and to applicable labeling requirements such as age grading, cautionary statements/warnings, instructional literature and item/model number or SKU.

5. Household Urban Hazardous Substances

- a. Shall be properly labeled in original packaging written in English or with English translation with the following minimum information:
 - full ingredient list,
 - manufacturing date,
 - batch or lot number
- b. Affidavit containing no banned ingredients

II. Health-Related Products

1. Ambulances and Mobile Clinics

- a. Preferably brand new; if second hand, shall be operational/functional, in good running condition, with mileage not exceeding 50,000 kilometers and not more than three years
- b. Shall have a Commercial Invoice or Certificate of Compliance to Emission Standards from country of origin
- c. Shall have left-hand drive positioning
- d. Shall have a local after-sales service provider, with spare parts, accessories and consumables that are locally available

2. Other Health and Health-Related Products

These are based on the criteria set by relevant agencies and evaluated on a case-to-case basis.

ANNEX C. DOCUMENTARY REQUIREMENTS FOR FOREIGN DONATIONS OF HEALTH AND HEALTH-RELATED PRODUCTS

1. Letter of intent/request addressed to the BIHC Director:

Director IV
Bureau of International Health Cooperation
Building 3, San Lazaro Compound, Rizal Ave.,
Sta Cruz, Manila, Philippines
Telephone No. (63 2) 6517800 local 1338/1310

2. Photocopy of the Authenticated (or Apostillized, if applicable) Deed of Donation by the Philippine Embassy/Consulate in the country of origin
3. Detailed List of items to be donated, to include the following information:
 - For pharmaceutical products- name of product, generic name or brand name, name and address of manufacturer, formulation, lot or batch number and expiry date, dosage form and strength
 - For devices- with detailed specifications, brand name, name of equipment, name and address of manufacturer, expiry date if sterile
 - For cosmetics- complete ingredients list, manufacturing date, batch/lot number
 - For processed food and food products- name of product, brand name, expiry/use by date, country of origin, complete ingredients list of each food product
 - For toys and childcare articles – name of product, age grading, cautionary statements/warnings, instructional literature and item/model number or SKU
 - For household/urban Hazardous Substances - complete ingredients list, manufacturing date, batch/lot number
4. Photocopy of pertinent certificates/documents, duly authenticated/apostillized from country of origin, or notarized if locally executed, as required in **Annex B**:
 - For pharmaceutical products – COPP/CFS
 - For devices – CFS, Certificate of Good Condition, if applicable
 - For toys and childcare articles – Certificate of Compliance to PNS-BHDT ISO 8124 or its accepted equivalent
 - For processed food and food products – CFS, Certificate of Quality
 - For ambulances and mobile clinics – Certificate of Compliance to emission standards
 - For household/urban Hazardous Substances – Affidavit containing no banned ingredients
5. Photocopy of the shipping documents- includes packing list, bill of lading/air waybill/sea waybill, commercial invoice
6. Letter of concurrence/acceptance from the recipient or consignee with strategic plans/development cooperation agenda of the recipient
7. Certificate of no commercial use and given for free or Notarized Affidavit of Undertaking indicating “not for commercial distribution or sale” duly signed by the recipient/consignee
8. Distribution/Allocation List/Plan

9. Proof of electronic submission of Post Donation Report* (if applicable) for succeeding Donations
10. Other relevant documents as may be required under special consideration such as waivers, list of identified patients, utilization report prior to the expiration of pharmaceutical products, etc.

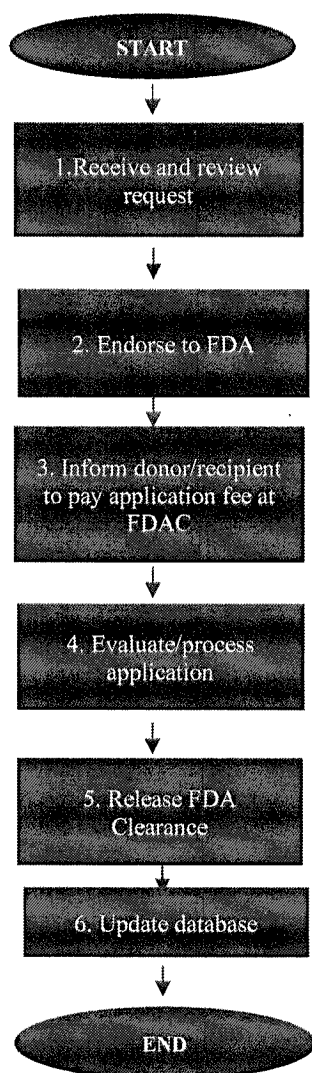
NOTE: Original documents such as, Apostillized Deed of Donation and Bill of lading/Air Waybill, Sea Way Bill will be requested once the request for DOH consignment will be approved

ANNEX D-1. PROCESS FLOW FOR NON-CONSIGNED DONATIONS

The process covers donations through importation of all pharmaceuticals, food, medical devices, cosmetics and health-related products registered and regulated by the Food and Drug Administration (FDA):

PROCEDURE/FLOWCHART

ACTIVITY



Activity	Timelines
1) Upon receipt of the request, the BIHC Process Owner (PO) reviews/evaluates the documents. If incomplete, inform the donor. Once complied, proceed to step number 2	Within one (1) day upon receipt
2) The BIHC PO endorses the request to FDA for the issuance of clearance	Within one (1) day upon receipt of complete documentary requirements
3) The BIHC PO informs the donor/recipient to pay the application fee at FDAC	Within one (1) day upon receipt of complete documentary requirements
4) The FDA PO technically evaluates the request based on the document submitted	Within three (3) working days or based on the approved Citizen's Charter of the concerned Office
5) The FDA PO release the clearance to the donor copy furnished BIHC	Within one (1) day upon receipt of the signed clearance
6) Update the database	Quarterly

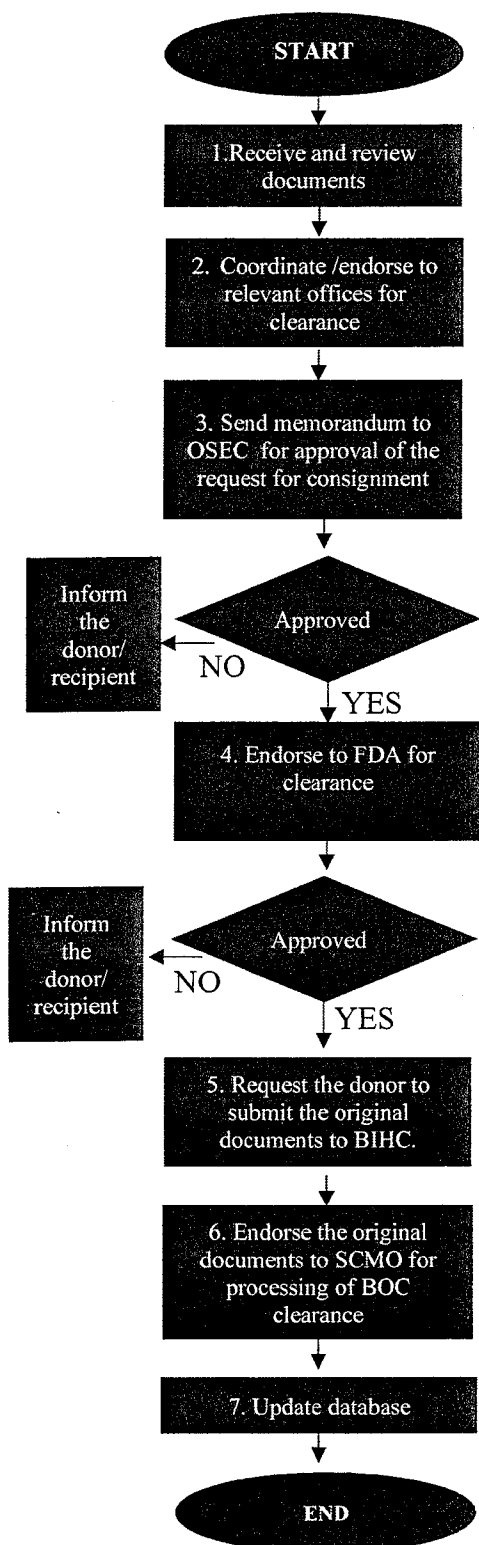
• SUBMISSION OF PDR

**ANNEX D-2. PROCESS FLOW FOR DOH CONSIGNED DONATIONS VIA
AUTOMATIC APPROPRIATION (DOH is consignee and DOH
shoulders taxes and duties)**

The process covers donations through importation of all pharmaceuticals, food, medical devices, cosmetics and health related products registered and regulated by the Food and Drug Administration (FDA):

PROCEDURE/FLOWCHART

ACTIVITY



Activity	Timelines
1) Upon receipt of the request, the Process Owner (PO) reviews the documents for completeness	Within one (1) day upon receipt
2) The PO endorses the request to relevant offices for the issuance of clearance, such LS, PD, HFDB, HFSRB, DPCB, PHST and others	Within one (1) day upon receipt of complete documentary requirements
3) Upon receipt of clearance, send memorandum to OSEC for approval of the request for consignment	Within two (2) days upon receipt of the clearance
4) Endorse to FDA if approved by OSEC. If disapproved, inform donor of the status.	Within one (1) day upon receipt of the approval/disapproval.
5) If FDA approved, request the donor to submit the original documents. If disapproved, inform the donor of the status.	Within one (1) day upon receipt of the approval/disapproval.
6) Endorse the original documents to SCMO for the preparation of BOC clearance.	Within one (1) day upon receipt of the original documents
7) Update the database	Quarterly

ANNEX E. POST DONATION REPORT

DOH-BIHC FD Form No. 1

[illegible]

[Handwritten signature]

II. General Assessment of the Donation	Yes	No	Remarks
• Is the donation appropriate to the hospital/facility?			
• Is the donation useful/needed by the hospital/health facility?			
• Was there a formal turnover of the donation?			
A. For Supplies and Medicines Donated			
• Do the supplies/materials have English translation?			
• Were there expired supplies/medicines received?			
B. For medical equipment and device donated			
• Is there manpower complement to operate the equipment/device?			
• Was training provided in operating/maintaining the equipment/device?			
• Is the health facility capable of fixing/replacing the donated equipment?			
III. Other Comments from the Recipient (please use additional sheet/s if necessary)			

Prepared by:

Noted by:

Name and Signature
Supply/Administrative
Officer

Name and Signature
Head of Facility/Organization

