

Republic of the Philippines Department of Health OFFICE OF THE SECRETARY

FEB 2 4 2016

ADMINISTRATIVE ORDER No. 2016-_ 0004

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

I. RATIONALE

The Department of Health (DOH), through the Bureau of International Health Cooperation (BIHC), currently facilitates all foreign donations following Administrative Order (AO) 54-A s. 2003, "Guidelines on the Processing and Clearance of Importations through Donation by the Department of Health." AO 54-A aims to rationalize and systematize the acceptance of foreign donations in support of the services and programs of the health sector. It is consistent and in accordance with the Tariff and Customs Code of the Philippines (TCCP) as amended, National Economic Development Authority (NEDA) Board Resolution No. 57 s. 1988, Office of the President Memorandum No. 36 s.1992, the 1999 World Health Organization (WHO) Guidelines for Drug Donations, and Section 13 of the General Appropriations Act (GAA) of 2002, under General Provisions on Donations.

Pertinent laws and guidelines relevant to the facilitation and management of foreign donations have been passed after 2003, such as Executive Order (EO) 482 of 2005 on the National Single Window, Republic Act (RA) 9711 – The Food and Drug Administration (FDA) Act of 2009, Department of Social Welfare and Development (DSWD) AO 11 s. 2012 "Revised Guidelines on the Management and Processing of Donation", Joint Circular No. 7 – 2012 of the Department of Budget and Management (DBM) and Department of Finance (DOF), and the annually approved General Appropriations Act specific issuances and provisions on donations Hence, there is a need for certain provisions of relevant post-2003 laws and guidelines on foreign donations to be incorporated and harmonized with the current guidelines of the DOH.

In the light of increased assistance from various international partners, the DOH recognizes the importance of strengthening existing systems in the facilitation and management of foreign donations. To address current gaps and issues identified in the processing and clearance of foreign donations, there is a need to institutionalize mechanisms to promote transparency, accountability, efficiency and responsiveness. There is a shift in the paradigm from the current donor-driven system of accepting foreign donations towards a health system needs-based approach.

II. OBJECTIVES

General Objective:

Enhance the systems involved in the facilitation and management of foreign donations

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Specific Objectives:

- Update and harmonize DOH guidelines on foreign donations with current relevant laws and guidelines
- Enhance the process involved in establishing the health system's needs prior to acceptance of foreign donations
- Establish the revised documentary requirements for the processing and clearance of foreign donations
- Establish an efficient and effective monitoring and evaluation system for foreign donations
- Identify the roles and responsibilities of different agencies and institutions involved in the facilitation and management of foreign donations

III. SCOPE AND COVERAGE

This AO shall apply to all individuals, organizations and institutions, both public and private, engaged in the initiation, facilitation and management of all donations of foreign origin covering all health and health related products during regular times. In times of emergencies and disasters, this AO shall not apply and instead, DOH AO 2007-0017, "Guidelines on the Acceptance and Processing of Foreign and Local Donations during Emergency and Disaster Situations" and/or other relevant existing guidelines shall be followed.

IV. DEFINITION OF TERMS

The following are the relevant terms used in the facilitation and management of foreign donations of health and health-related products.

- 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 responsibility 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.
- Airway Bill is a document issued by an air carrier or freight forwarder to a shipper as an
 evidence of contract of carriage by air. It acknowledges that an airline received the cargo,
 and provides instructions on cargo handling, dispatch and delivery.
- Automatic Appropriation for the purpose of this AO, refers to the appropriation
 programmed annually for the DOH and stipulated as a line item under the GAA, wherein the
 payment of duties and taxes for foreign donations consigned to the DOH is charged.
- 4. Bill of Lading refers to a written contract between the shipper and the carrier indicating receipt of commodities and constitutes a title of ownership over said goods. It indicates the name of the consignee, destination, freight charges and description of the goods i.e. quantity, weight dimension, volume, identification and condition.
- Certificate of Free Sale (CFS) is a certificate indicating that the goods are normally sold in the open market and approved by the regulatory authority in the country of origin.
- Deed of Acceptance is a duly notarized document signed by the donce, recipient or consignee formally accepting the donation.

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- Deed of Donation is a duly authenticated document or instrument (authentication done
 by the Philippine Embassy/Consular Office at the country of origin), which when
 delivered gratuitously transfers ownership and interests in property to persons and/or
 entities.
- 8. National Single Window is an Internet-based system that allows parties involved in trade to lodge information and documents with a single entry point to fulfill all import, export, and transit-related regulatory requirements whose aim is to create a more efficient process for the importation and export of goods and to lessen the bureaucratic red tape in government agencies.
- 9. Packing List is a shipping document that contains the quantity and kinds of packages, their contents, the net and gross weight in kilograms, the full dimensions 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.
- 10. Pro Forma Invoice is a draft invoice given by the shipper/donor to an importer/donee/ recipient/consignee prior to the shipment of goods. It provides information on the nature, quantity, value and weight of goods to be donated.

V. GENERAL GUIDELINES

- All donations shall be based on the following four core principles, as stipulated in the WHO 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
- All foreign and foreign-based Filipino donors shall abide by the existing national laws and regulations of the Philippines and shall be guided by the Paris Declaration on Aid Effectiveness, emphasizing alignment of donor systems to the procedures of recipient countries.
- 3. All donations shall be aligned with DOH thrusts and programs.
- All donations shall be based on the actual expressed needs of recipients, rather than being donor-driven.
- All offers of foreign donation shall be processed on a per shipment basis. The acceptance of donations should consider expiration dates that will allow adequate time for distribution and utilization among beneficiaries.
- All donations shall preferably be brand new.
- 7. Proper clearances and approval shall be obtained from relevant agencies prior to shipment and are subject to inspection upon arrival. All required documents must be submitted prior to the release of any foreign donation to recipients. In cases of undeclared goods upon inspection, the donor shall be meted with a corresponding penalty and shall be blacklisted.
- 8. All donations are subject to customs duties, taxes and other fees and charges and therefore, not accepted for free. 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 must be established before shipment is made.
- The consignee is deemed the owner of the donation and shall pay the taxes and duties and all other shipping costs unless there are other arrangements.

10. 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.

VI. SPECIFIC GUIDELINES

A. REQUIREMENTS/CRITERIA FOR FOREIGN DONATIONS

- The DOH shall accept the following goods and items as donations:
 - Health products such as pharmaceuticals, medical equipment and devices, and medical supplies
 - b. Health related products such as ambulances, mobile clinics, etc.

c. Other health and health related products

The donations shall fulfill the criteria outlined in Annex A prior to acceptance.

3. The following products are NOT acceptable for donations:

a. Expired, spoiled or deteriorated products

b. Product with expiration date below 12 months from the expected time of arrival in the country

c. Products with literature without English translation

d. Drugs not included in the latest edition of the Philippine National Formulary

- e. Incompletely labeled drugs or those not bearing the following labeling information : name of product (generic name or brand name), dosage form/ strength, name and address of manufacturer, formulation, lot or batch number, expiration date)
- f. Products which are not in original packaging, or have been partly used except for medical equipment/devices which may be second hand but certified to be functional, in an operating condition and not more than (2) two years old

g. Products included in the list of prohibited and contraband list prepared by the

- h. Drugs included under the regulated, prohibited and/or dangerous drugs and exempt preparations list of the Philippine Drug Enforcement Agency (PDEA)
- i. Experimental /investigational drugs and drugs containing active ingredient/s not found in any currently registered drug product

Food supplements and related products

- 4. Acceptance of donations in the following instances shall be given due consideration:
 - a. Drugs and medicines not listed in the current edition of the PNF but with a local counterpart that is FDA registered

b. Orphan drugs and drugs for compassionate use

c. Other critically needed drugs as justified, subject to approval of relevant agencies e.g. Pharmaceutical Division and FDA.

B. CATEGORIES OF FOREIGN DONATIONS

Upon receipt of the letter of intent to donate, the DOH-BIHC 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. A table of categories is outlined in Annex B. The types and categories of foreign donations are as follows:

1. Foreign Donations Not Consigned to the DOH

Recipients of these donations would include private institutions, NGOs, LGU facilities and other non-DOH retained public facilities. All taxes, fees or duties are either paid by the donor or the recipient.

2. Foreign Donations Consigned to DOH

Donations consigned to the DOH are approved by the Secretary of Health on a per shipment basis. Customs duties and import taxes are paid by 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 and retained hospitals. DOH facilitates the donations' clearance, release, distribution and delivery through its official broker. DOH has the prerogative to decide on where to distribute the donated items.

b. DOH Consigned but non-DOH Managed Foreign Donations

These are donations intended for non-DOH institutions like LGUs, NGOs and non-profit health facilities but are consigned first to the DOH under special circumstances. This consignment may be approved by the Secretary of Health only if the donation is not for commercial use and offered to be used by the LGU/NGO for free. Other fees and charges such as brokerage, storage, handling, demurrage, etc., are paid by either the donor or recipient. The recipient is responsible for the management of the donation.

3. Foreign Donations Accompanying Foreign and Surgical Medical Missions

These are donations to be utilized in duly cleared foreign surgical and medical missions. Importation costs are paid by either the missioners or local beneficiaries unless if it is under the "Adopt-a-Hospital" Program as stipulated in AO 2012-0030, where DOH shoulders the importation costs.

4. Foreign Donations under Foreign Assisted Projects

These are donations facilitated through development partners, as part of the implementation of FAPs. The customs duties, import taxes and all other fees are covered by either donor (development partner) or recipient (DOH), as stated in the Project financing agreement.

5. Foreign Donations during Emergencies and Disasters

These are donations facilitated in times of emergencies, disasters and calamities. The customs duties and import taxes are shouldered by the government through relevant mechanisms, such as, but not limited to, charging to the Office of the President under PMO 36, the concerned National Government Agency or the One Stop Shop facility established at the major ports.

C. BASIC PROCESS OF FACILITATION AND MANAGEMENT OF FOREIGN DONATIONS

All foreign donations shall undergo the following basic processes:

Step 1. Securing of initial clearance from the DOH for acceptance of donation

Step 2. Submission of complete documentary requirements by the donor

Step 3. Shipment of foreign donation

Step 4. Processing and endorsement of original documents to DOH relevant offices

Step 5. Inspection and final clearance by FDA

Step 6. Release and turn over to consignce

Step 7. Monitoring and evaluation

Except for donations made during emergencies and disasters, the entire process of facilitation of foreign donations takes about two to three months, including shipment. The DOH processes for clearance require at least one month. Hence, it is ideal that all foreign donations are processed three (3) months before the projected turn-over date. The detailed instructions for each of these steps are further claborated in Annex C and posted in the DOH website. The DOH Technical Working Group (TWG) created for the purpose of evaluating compliance to set criteria and establishing the need for such donation, will review the documents.

VII. ROLES AND RESPONSIBILITIES

1. BUREAU OF INTERNATIONAL HEALTH COOPERATION

- Act as the over-all coordinator for the facilitation and management of foreign donations
- b. Ensure that donations are aligned with the DOH's thrusts and program strategies

c. Review completeness and authenticity of submitted documents

- Ensure proper coordination with and endorsement to relevant offices/agencies for the efficient facilitation of donations
- Notify and coordinate with donors regarding clearances, requirements and status of offers of foreign donations
- f. Act as the Convenor/Secretariat of the TWG created to evaluate proposed DOHconsigned foreign donations in terms of need and compliance to set criteria
- g. Establish, maintain and update a database of all foreign donations for monitoring and reporting purposes
- Together with the RO, conduct regular monitoring visits to recipient facilities and institutions
- Ensure the adequate dissemination of the AO to relevant organizations and other interested parties, to include the posting of this AO at the DOH website
- j. Develop, review and update guidelines, as necessary

2. LOGISTICS MANAGEMENT DIVISION

- a. Act as a member of the TWG for the evaluation of proposed DOH consigned foreign donations in terms of need and compliance to set criteria
- Coordinate with and regularly update the BIHC regarding the status of all DOH consigned donations
- Coordinate with relevant agencies to facilitate the clearance and release of all foreign donations consigned to DOH
- d. Prepare the Deed of Undertaking and ensure delivery, proper turnover and distribution 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

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g. Prepare the Invoice Receipts for the distribution/turnover of the foreign donations to recipients

h. Furnish the BIHC and the Finance Service of the copies of the Invoice/Delivery

Receipts duly signed by recipients

 Together with BIHC, review and update guidelines relevant to the processing and management of foreign donations

3. FOOD AND DRUG ADMINISTRATION

 Act as a member of the TWG for the evaluation of proposed DOH consigned foreign donations in terms of need and compliance to set criteria

 Issue an initial clearance for the acceptance of proposed foreign donations consigned to DOH

c. Issue the FDA clearance to BOC for the release of the foreign donation from the consignee's warehouse for non-DOH-managed donations

 d. Conduct physical inspection and collect samples for FDA analysis (for food and medicines)

 Conduct actual testing on the functionality of medical equipment and devices consigned to DOH

f. Issue the Certificate of Product Registration, if applicable

g. Ensure that relevant FDA policies are updated and disseminated

4. PHARMACEUTICAL DIVISION

 Act as a member of the TWG for the evaluation of proposed DOH consigned foreign donations in terms of need and compliance to set criteria

b. Review list of medicines intended for foreign donations and issue initial clearance for the acceptance of proposed foreign donations based on the PNF List and their existing guidelines

c. Develop and update guidelines on foreign donations for orphan drugs

d. Develop and issue advisories in the rational use of medicines

5. HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

 Act as a member of the TWG for the evaluation of proposed DOH consigned foreign donations in terms of need and compliance to set criteria

b. Validate the list of equipment needed by the DOH recipient facilities based on

the set standards for hospitals. Please refer to "Annex C."

6. HEALTH FACILITY DEVELOPMENT BUREAU

 Act as a member of the TWG for the evaluation of proposed DOH consigned foreign donations in terms of need and compliance to set criteria

 Make recommendations on the need for medical equipment and devices of health facilities using the Health Facility Enhancement Program of the DOH as basis

7. FINANCE SERVICE

a. Facilitate special allotment release order request to the DBM for the automatic appropriation and charging of customs duties and import taxes of DOH Consigned donations

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 Ensure proper accounting and reporting of donations as required by government accounting and auditing rules and regulations

8. DOH REGIONAL OFFICES

- Validate the need for the foreign donation of the DOH recipient facility under its jurisdiction based on checklist/criteria set for accepting foreign donations
- Coordinate with BIHC and the recipient institution the conduct of turn over if applicable
- c Follow- up submission of Post Donation Report within 30 days after the turn over of the donation. Please refer to "Annex D."
- d. Conduct monitoring of foreign donations to DOH recipient facilities
- Ensure integration of policy dissemination/advocacy on foreign donations in the activities/programs of the Region

8. COMMISSION ON FILIPINOS OVERSEAS (CFO)

- a. Coordinate with and refer to BIHC all offers/intents/requests for foreign donations
- Conduct policy dissemination/advocacy activities on foreign donations to prospective donors

A. PHILIPPINE EMBASSIES/CONSULATES

- a. Provide information to prospective donors on the Foreign Donation program e.g. requirements, processes
- Authenticate the Deed of Donation and other required documents submitted by prospective donors
- c. Ensure the adequate dissemination of the AO to relevant organizations and other interested parties, to include the posting of this AO and its updated versions in their Embassy website

10. DONOR

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- a. Comply with the process/procedures of facilitation and management of foreign donations referred to in "Annex C."
- b. Ensure the submission of all relevant documentary requirements
- Coordinate with the Philippine Embassy/Consulate to initiate the donation process and authentication of the Deed of Donation and other relevant documents
- d. Coordinate with recipients to inform them of the donation and to make the necessary arrangements for the processing, release and turn-over of the donation
- e. Together with the donee/recipient, 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

12. DONEE/RECIPIENT

- 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

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ANNEX A. REQUIREMENTS/CRITERIA FOR FOREIGN DONATIONS

I. Health Products

1. Pharmaceuticals

a. Must be of good quality

b. Be in good condition, not adulterated nor misbranded

c. Contains the same active ingredients as those already registered with the FDA

d. Have an expiration date not less than 12 months upon arrival in the country

e. Properly labeled in original packaging

f. Literatures and texts must be in English or should 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)

 Must have a Certificate of Approval/CFS by a regulatory body from the country of origin

Must be included in the latest edition of the PNF

- Must conform to regional harmonized guidelines set by the Association of Southeast Asian Nations
- Not included in the list of experimental/investigational drugs and drugs containing active ingredient(s) that are under the FDA Monitored Release Registration

k. Not under the contraband list prepared by NEDA

 Not included in the list of regulated, prohibited and/or dangerous drugs and exempt preparations list of the Philippine Drug Enforcement Agency (PDEA)

Due consideration shall be given in the following circumstances:, (i) Drugs and medicines not listed in the current edition of the PNF but with a local counterpart that is FDA registered, (ii) Orphan drugs and drugs for compassionate use, and (iii) Other critically needed drugs as justified, subject to approval of relevant agencies e.g. Pharmaceutical Division and FDA.

2. Medical Equipment and Devices

- Must meet standards promulgated by international bodies, such as ISO Certification
- b. Preferably brand new; 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. Must have a CFS issued by a regulatory body from the country of origin

d. Must have a certificate of calibration, if applicable (e.g. sphygmomanometer)

e. Must have warranty card applicable in the Philippines, if brand new

- f. Must be accompanied by Invoice Receipt (from original acquisition) or Manufacturers Certificate, if second hand
- g. Must have a local after-sales service provider, with spare parts, accessories and consumables that are locally available and affordable

h. Must be accompanied by provision of training for the end-users, as necessary

- Must have a complete operational manual/brochure written in English or with English translation
- Power supply must conform with Philippine national standards (220/240volts, 60 hertz)

k. Must be mercury-free

1. Must be chlorofluorocarbon (CFC) free

3. Medical Supplies

a. Must meet standards of international bodies, such as ISO Certification

·b. Must not be expired

- c. Must be accompanied by technical specifications/dossier
- d. Must be mercury free/CFC free, if applicable

II. Health Related Products

1. Ambulances and Mobile Clinics

- a. Preferably brand new; if second hand, must be operational/functional, in good running condition, with mileage not exceeding 50,000 kilometers and not more than three years
- Must have a Commercial Invoice or Certificate of Registration from country of origin
- Must have a recent Certificate of Quality Control/Certificate of Compliance to Emission Standards from country of origin
- d. Must have left-hand drive positioning
- e. Must 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 shall be based on the criteria set by relevant agencies and evaluated on a case-to-case basis.

ANNEX B. TABLE OF CATEGORIES OF FOREIGN DONATIONS

Туре	Payer of Import and Customs Tax	Payer of Brokerage, Demurrage, Etc.	Recipient	Manager	Remarks	
A: Not DOH Consigned	Donor or Recipient	Donor or Recipient	LGU, NGOs, non-DOH facilities	Recipient	Only FDA clearance is needed from DOH	
B. DOH Consigned and Managed	DOH	DOH	DOH, DOH retained hospitals, DOH attached agencies	Recipient	Consignment needs approval of the Secretary of Health	
C. DOH Consigned but non- DOH managed	DOH	Donor or Recipient	RHUs, LGUs, other public health facilities, non- profit NGOs	Recipient	Consignment needs approval of the Secretary of Health	
D. Donations Accompanying Foreign Missioners	Donor or Missioners	Donor or Missioners	LGU, NGOs, non-DOH facilities, Patients	Recipient	Generally, duties and taxes for this type of donation will be paid by donor/recipient except, if the mission/donation is under the Adopt a Hospital Program A.O 2012-0030 wherein the DOH pays the duties and taxes	
E. For Foreign Assisted Projects	Payer of Fees and management of the foreign donation will depend on the Financing Agreement of the Foreign Assisted Project.					
F.For Emergency Situations	DOH or Office of the President under PMO 36, with or without One Stop Shop Facility established at major ports	DOH or other concerned National Government Agency	Disaster affected health facilities and patients	DOH or Donor or Recipient	AO 2007-0014 is applicable, as well as other relevant existing guidelines on disaster situations	

ANNEX C. DETAILED PROCESS OF FACILITATION AND MANAGEMENT OF FOREIGN DONATIONS

STEP 1. SECURING INITIAL CLEARANCE FOR ACCEPTANCE OF DONATION FROM DOH

Donor submits to the DOH-BIHC the following documents:

a. Letter of Intent to Donate addressed to:

The Secretary of Health

Attention: Director IV, Bureau of International Health Cooperation

Bldg. 3, San Lazaro Compound

Rizal Ave., Sta. Cruz, Manila

- b. List of items to be donated/Packing List, providing the following minimum information, taking into consideration the requirements/criteria set in Section A:
 - b.1. For pharmaceuticals Generic name, dosage, form and strength, quantity and expiration date
 - b.2. For medical equipment and devices Technical specification, model number, manufacturing date and invoice receipt or certificate of good operating/functional condition (if second hand), and brochures ard manuals written in English
 - b.3. For transport vehicles Certificate of Registration from country of origin, mileage information and photo of ambulance or mobile clinic

b.4. For food - Quantity and expiration date

c. Letter of Concurrence/Acceptance from the recipient/beneficiary

- BIHC acknowledges receipt of letter and other documents and evaluates the request and its attachments as to completeness and conformity to the set criteria.
 - a. If there is no intent for consignment to DOH and found in compliance with existing requirements, BIHC endorses the documents to relevant offices (i.e. FDA, PDEA, Pharmaceutical Division) for the issuance of initial clearance for acceptance of donation.

 If foreign donation is intended for consignment to DOH, the BIHC will seek the approval of the Secretary of Health.

The TWG, through the BIHC, shall then make a recommendation to the Office of the Secretary regarding the acceptance or non-acceptance of the foreign donation. Upon receipt of the OSEC decision, BIHC informs the donor of the decision, as well as further requirements and next steps to be undertaken.

STEP 2. SUBMISSION OF DOCUMENTARY REQUIREMENTS

- i. Upon receipt of the approved initial clearance (for regular non-DOH consigned donations) or OSEC approval for consignment (for DOH consigned donations), the donor proceeds with the processing and submission of the following documentary requirements to the BIHC:
 - a. Original copy of the Deed of Donation duly authenticated by the Philippine Embassy/Consular Office at the country of origin
 - Original copy of shipping documents such as bill of lading, air way bill, pro forma or commercial invoice (if already available)
 - c. Proposed allocation list
 - d. Affidavit/Deed of Undertaking, if necessary
 - Designation letter of authorized broker (for DOH consigned but non-DOH managed foreign donations)
- BIHC acknowledges receipt of documentary requirements and evaluates them as to completeness and veracity prior to processing.

a. For all donations consigned to DOH, the consignee details should appear as:

Department of Health - Philippines c/o (name of) Secretary of Health

San Lazaro Compound, Sta. Cruz, Manila, Philippines

b. Only donations with the DOH as the consignee will be accepted and processed es a DOH consigned donation (Category B.2.). If the donation is intended to be consigned to the DOH and the consignee's name that appears in the documents is <u>not</u> the DOH, it is the responsibility of the donor or the recipient to amend the consignee's details for further processing of duties and taxes exemption.

STEP 3. SHIPMENT OF FOREIGN DONATION

- i. Once documentary requirements are submitted and evaluated, the donor proceeds with the shipment (cither by sea or air) of the donation and submits to BIHC the original copies of the shipping documents. For DOH consigned donations, approval of consignment by the Secretary of Health must be secured in writing before shipping in order to avoid problems and unnecessary charges. Once approved, the BIHC will inform the donor of such approval and advise to proceed with the shipment and likewise submit original copies of the shipping documents and the authenticated Letter of Donation from the Consular Office of the Country of Origin for processing of customs clearance.
- ii. The donor then informs the BIHC on the projected arrival of the foreign donation/s.
 iii. The BIHC notifies the FDA and the DOH Logistics Management Division (DOH-LMD) for coordination with port authorities regarding the arrival of the donations.

STEP 4. PROCESSING AND ENDORSEMENT OF ORIGINAL DOCUMENTS TO RELEVANT DOH TECHNICAL OFFICES

While shipment is in transit, further processing and endorsement of original documents to relevant government clearing agencies shall be undertaken, depending on the type and purpose of the donation.

a. For Foreign Donations Not Consigned to DOH

- Upon receipt of the complete documentary requirements, BIHC endorses to FDA for technical evaluation.
- BIHC informs the donor and/or beneficiary to coordinate directly with FDA for the issuance of FDA clearance for Customs Release.
- Upon receipt of FDA clearance, donor and/or beneficiary proceeds with the processing of DOF/BOC clearances and payment of VAT.

b. For Foreign Donations Consigned to DOH

- Upon receipt of the complete documentary requirements, BIHC endorses copies
 of the documents to the FDA for technical evaluation and the issuance of FDA
 clearance needed for Customs Release.
- ii. BIHC then endorses the original copies of the complete documentary requirements to the DOH-LMD for processing of customs clearance and release and for further coordination with the official DOH broker and forwarder (for DOH managed donations) or the identified authorized broker of the donor or the recipient (for non-DOH managed donations).

c. For Foreign Donations Accompanying Foreign Surgical and Medical Missions

 Donations to be used for FSMM which are consigned to the donor and/or beneficiary shall follow the same procedures under Step 4, letter a, stated as "Foreign Donations Not Consigned to DOH".

ii. Donations under the "Adopt a Hospital Program" wherein DOH is the consignee shall follow the same procedures under Step 4, letter b, stated as "Foreign Donations Consigned to DOH".

d. For Foreign Donations under Foreign Assisted Projects

Donations under FAPs shall also follow procedures in Step 4, letter a, if it is consigned to the concerned donor and Step 4, letter b, if it is consigned to the DOH.

e. For Foreign Donations during Emergencies and Disasters

Donations intended for victims of emergencies and disasters shall follow DOH AO 2007-0017, "Guidelines on the Acceptance and Processing of Foreign and Local Donations during Emergency and Disaster Situations" and/or other relevant existing guidelines. It shall be processed accordingly, such as, but not limited to, charging of customs duties and import taxes to the Office of the President under PMO 36, or the concerned National Government Agency at the One-Stop-Shop facility established at the major ports.

STEP 5. INSPECTION AND FINAL CLEARANCE BY FDA

- ii. Upon arrival at the port of entry, the FDA conducts an initial physical inspection as a requirement for the release from the port of the donated pharmaceuticals and medical devices and equipment. If the port of entry of the donation is outside Metro Manila, the said inspection shall be conducted by the concerned Regional FDA office.
- Aside from inspection, the FDA also collects samples of pharmaceuticals at the consignee's warehouse for analysis.
- iv. For medical equipment and devices, the FDA conducts actual testing on the functionality of the donated items at the recipient facility, prior to issuance of necessary licenses.
- v. If the FDA finds the donated items acceptable for donation after inspection, the FDA issues a final clearance for the release of the donated health and health related products. No donation shall be released from any warehouse and distributed without the FDA clearance.

STEP 6. RELEASE AND TURN OVER TO CONSIGNEE

- The DOH-LMD is responsible for the delivery, proper turnover and distribution to
 the ultimate recipients of DOH consigned and managed donations once released
 from the port by the BOC. It issues an Invoice Receipt which will be signed by the
 recipient for accounting and monitoring purposes.
- ii. For DOH consigned but non-DOH managed donations, the DOH-LMD coordinates with the identified authorized broker of the donor or recipient regarding the DOH payment of customs duties and import taxes and the release of the shipment. The broker must submit to the DOH-LMD a Delivery Receipt for accounting and monitoring purposes.

- The BOC then releases the donation to the consignee after all necessary clearances are obtained.
- A formal or ceremonial turn-over may be organized and conducted by the donor and/or recipient.
- iv. Items that were included in the shipment but were not declared in the Packing List shall be placed under the ownership of the DOH for further evaluation, distribution, utilization and/or disposal.

STEP 7. MONITORING AND EVALUATION

- i. The recipient and/or consignee must submit to the DOH-BIHC a Post-Donation Report, copy furnished the concerned DOH-Regional Office (RO), within 30 day's after the turn over and/or issuance of invoice/delivery receipt. Non-submission of post-donation report shall be a ground for non-issuance of succeeding clearances.
- The BIHC creates/updates a list of donors who will be blacklisted for donating expired medicines or unserviceable/non functional medical equipment and devices. They shall not be issued subsequent clearances.
- BIHC and/or the concerned DOH-RO shall conduct regular monitoring of foreign donations as to distribution, utilization and/or disposal.
- BIHC shall maintain a database of foreign donations for analysis and basis for future policy recommendations.

ANNEX D. POST-DONATION REPORT FORM

The state of the s			DOH-BIHC FD Form No. 1	
Name of Recipient/Institution		- 		
vame of Donor			-	
Date of Receipt of Donation				
Received By: Name				
Position				
Contact Number		Email Address		
Donated Item	Quantity	Condition upon Receipt	Remark	
3355 2500 2500				
Please attach supporting docum	nents (i.e. Invoice	Receipt, Delivery Receipt) as appropriate		

• Is the donation appropriate to the	e hospital/health facility?		
• Is the donation useful/needed by	the hospital/health facility?		
· Was there a formal turnover of t	he donation?		
		137-72	
• Do the supplies/materials have I	inglish translation?		
· Were there expired supplies/med	dicines received?		
		And	
* Is there manpower complement	to operate the equipment/device?		
Was training provided in operation	ng/maintaining the equipment/device?		
	ixing/replacing the donated equipment?		
	The second second		
		1111	
Prepared by:	Noted by:		
	rocks by.		
	20		
Name and Signature	Name and Signature	Name and Signature	
Supply/Administrative	Head of Facility/Organization		