



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

FEB 24 2016

ADMINISTRATIVE ORDERNo. 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

7. **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

1. 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
2. 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.
4. All donations shall be based on the actual expressed needs of recipients, rather than being donor-driven.
5. 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.
6. 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.
9. 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.

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 missionaries 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

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

3. FOOD AND DRUG ADMINISTRATION

- 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
- b. 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)
- e. 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

- 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
- 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

- 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
- 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

- 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
- b. 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

- 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.) relative to the donation, if not consigned to the DOH
- 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 RO, 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 D".

~~VIII~~ ~~XII~~ **SEPARABILITY CLAUSE**

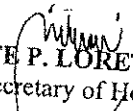
If any provision of this AO is declared invalid or unconstitutional by the appropriate authority or courts of law respectively, the other provisions not affected thereby shall remain valid and subsisting.

~~IX~~ ~~XI~~ **REPEALING CLAUSE**

This Administrative Order repeals AO No. 54-A s. 2003.

~~X~~ ~~XII~~ **EFFECTIVITY DATE**

This Order shall take effect fifteen (15) days after publication in an official gazette or a newspaper of general circulation.


JANETTE P. LORETO-GARIN, MD
 Secretary of Health

- 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
- b. Must have a Commercial Invoice or Certificate of Registration from country of origin
- c. 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 C. DETAILED PROCESS OF FACILITATION AND MANAGEMENT OF FOREIGN DONATIONS

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

- i. 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 and 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
- ii. 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.
 - b. 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
 - b. 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
 - e. Designation letter of authorized broker (for DOH consigned but non-DOH managed foreign donations)
- ii. BIHC acknowledges receipt of documentary requirements and evaluates them as to completeness and veracity prior to processing.

- c. For Foreign Donations Accompanying Foreign Surgical and Medical Missions**
- i. 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.
- iii. 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

- i. 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 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.

ANNEX D. POST-DONATION REPORT FORM

DOI-BIHC FD Form No. 1

| Name of Recipient/Institution | | | |
|--|----------|------------------------|---------|
| Name of Donor | | | |
| Date of Receipt of Donation | | | |
| Received By: | Name | | |
| | Position | | |
| Contact Number | | Email Address | |
| | | | |
| Donated Item | Quantity | Condition upon Receipt | Remarks |
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| <p>**Please attach supporting documents (i.e. Invoice Receipt, Delivery Receipt) as appropriate</p> | | | |

Documentary Requirements for the conduct of Foreign Surgical and Medical Missions

Letter of Request

Indicate type (medical, surgical, dental), date and exact venue of mission. Please address the letter to:

MS. MAYLENE M. BELTRAN, MPA, CESO III
Director IV
Bureau of International Health Cooperation

Special Temporary Permits (STPs)*

Provide scanned copies of STP Resolutions as issued by the Professional Regulation Commission.

Letter of Acceptance/Confirmation from Local Partner

Confirm to DOH – BIHC the place, date, time and duration of mission. Include a list of all members of the mission. Please address the letter to:

MS. MAYLENE M. BELTRAN, MPA, CESO III
Director IV
Bureau of International Health Cooperation

Post Mission Report

Submit to DOH Representative (Regional Office) a post-mission report within 15 days after the mission for onward transmittal to DOH-BIHC

Checklist of Requirements for the Application of Special Temporary Permits (STPs)

- Letter of Request for the issuance of STP with undertaking that no fees shall be charged to patients. The letter must indicate the **specific date, venue and type of humanitarian mission** (medical, surgical, dental). Please address letter to:

Hon. Teofilo S. Pilando, Jr.
Chairman
Professional Regulation Commission
P. Paredes St. cor. Morayta St.
Sampaloc, Manila

Tel. (632) 3100026
Telefax (632) 7354476
www.prc.gov.ph

- Copy of applicant's valid passport as proof of citizenship
- Authenticated Copy of valid professional license issued from the country of origin with official English translation, if necessary
- Duly accomplished and notarized STP application form



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Code: 2016 FDR _____

**Donor's Checklist For Foreign Donations Seeking
Food and Drug Administration Clearance :**

Submit to Bureau of International Health Cooperation (BIHC) the following documents for processing of request for FDA clearance:

1. Letter /email of intent/request addressed to
Dir. Maylene Beltran
Director IV
Bureau of International Health Cooperation
Building 3, San Lazaro, Compound, Sta. Cruz,
Manila, Philippines
Telephone No. (63 2) 6517800 local 1302/1352
Email address: mbeltran.bihc@gmail.com
2. Detailed list of items to be donated
For medicines - with 12 months minimum expiration date, properly labeled in original packaging, with texts in English
For medical equipment and devices - with detailed specifications, of quality, if second hand, must be certified to be in good operating/functional condition
3. Distribution Plan of Commodities
4. Deed of Acceptance from the recipient/beneficiary facility
5. Deed of Donation duly authenticated by the Philippine Embassy /Consulate in the Country of Origin
6. Shipping documents -- includes packing list, bill of lading/air waybill, commercial invoice