



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

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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 Imports 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

2. Enhance the process involved in establishing the health system's needs prior to acceptance of foreign donations
3. Establish the revised documentary requirements for the processing and clearance of foreign donations
4. Establish an efficient and effective monitoring and evaluation system for foreign donations
5. 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.
2. **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.
3. **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.
5. **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.
6. **Deed of Acceptance** – is a duly notarized document signed by the donee, recipient or consignee formally accepting the donation.
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 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.
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

1. The DOH shall accept the following goods and items as donations:
 - a. 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
2. 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 a operating condition and not more than (2) two years old
 - g. Products included in the list of prohibited and contraband list prepared by the NEDA
 - 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
 - j. 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 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
- 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 consignee
- 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 elaborated 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

- a. 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
- 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. Act as the Convenor/Secretariat of the TWG created to evaluate proposed DOH-consigned 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
- h. Together with the RO, conduct regular monitoring visits to recipient facilities and institutions
- i. 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
- 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. 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

- 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

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

8. DOH REGIONAL OFFICES

- a. Validate the need for the foreign donation of the DOH recipient facility under its jurisdiction based on checklist/criteria set for accepting foreign donations
- b. 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
- e. Ensure integration of policy dissemination/advocacy on foreign donations in the activities/programs of the Region

9. COMMISSION ON FILIPINOS OVERSEAS (CFO)

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

10. PHILIPPINE EMBASSIES/CONSULATES

- a. Provide information to prospective donors on the Foreign Donation program e.g. requirements, processes
- b. 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

11. DONOR

- 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
- c. 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

- 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. SEPARABILITY CLAUSE

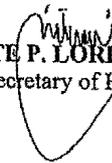
If any provision of this AO is declared invalid or unconstitutional by the appropriate authority or courts of law respectively, the other provisions not affected thereby shall remain valid and subsisting.

IX. REPEALING CLAUSE

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

X. 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