



**Ethiopian Food, Medicine and Healthcare Administration and Control
Authority**

Medical Equipment Donation Directive

December 2012

Addis Ababa

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Preamble

WHEREAS, medical equipment has significant contribution to the improvement of quality healthcare service;

WHEREAS, it is found necessary to protect the community from unsafe, incompatible, non functional, substandard and outdated medical equipment by ensuring the safety, usability and quality of donated medical equipment and make sure they have the necessary installation or service manual, spare parts and continuity of maintenance;

WHEREAS, it is found necessary that medical equipment donation must be based on sound analysis of the need of recipients and the selection and distribution shall observe existing policies and laws of the country;

NOW, THEREFORE, with a view to rectify the existing donation practice; this directive is issued in accordance with Article 55 (3) of the Food, Medicine and Healthcare Administration and Control Proclamation No.661/2009.

Part One

General

1. Short Title

This directive may be cited as the “Medical Equipment Donation Directive No. 9/2012”

2. Definitions

Without prejudice to the definitions provided under Proclamation No 661/2009, in this directive, unless the context otherwise requires;

1. “Medical equipment” means any instrument that may be used on the inner or outer part of the body for diagnosis or treatment of a disease in human. This includes various diagnostic, laboratory, surgery and dental medical instruments;
2. “Donation” means an act or instance of presenting medical equipment to recipients in emergency or as a part of development aid in non emergency situation;
3. “Donor” means a governmental or nongovernmental organization or individual who voluntarily donates medical equipment as a donation;
4. “Recipient” means a governmental, non-governmental or private health institution that voluntarily receives medical equipment as a donation;
5. “Authority” means the Ethiopian Food, Medicine and Healthcare Administration and Control Authority

3. Objective

The objective of this directive shall be:-

1. to protect and promote the health of the community by ensuring the safety, usability and quality of donated medical equipment;
2. to alleviate problems associated with donation by promoting good medical equipment donation practice;
3. to make sure donated equipments are in compliance with the need of the country;
4. to provide rights and responsibilities of the donor and recipient; and
5. to control importation of unwanted medical equipment as well as minimize the accumulation of non-functional medical equipment.

4. Scope of Application

This directive shall be applicable to all donated medical equipments.

5. Principle

1. Donation shall be in accordance with the recipient's need and comply with the existing government health policies, laws, guidelines and administrative arrangements.
2. Donation shall comply with applicable standards and there shall be no double standards regarding quality of donated items. Equipment unacceptable in the donor country shall not be accepted.
3. Donation shall support and enable recipients to promote the quality of health services.

Part Two

Requirements for Donation

6. General Requirements

1. No medical equipment shall enter in to the country without prior permission of the Authority.
2. Recipient shall not receive and import medical equipment donation without the prior approval of the Authority.
3. No medical equipment shall be donated if it was collected from unknown source, sent without prior communication between the recipients and donors or given to health professionals as free samples.
4. If the equipment is used it shall be reconditioned, tested and all essential parts, accessories and working materials included before shipment.
5. No medical equipment may be donated if the equipment has been in use for more than five years.

7. Pre-import Permit

1. Anyone who wants to import or receive medical equipment as a donation shall have a pre-import permit from the Authority.
2. Any person who seeks pre-import permit shall submit an application in 4 duplicates to the Authority in accordance with the provided Annexes.
3. The applicant, together with the application, shall submit:
 - a. an agreement entered into between the donor and recipient;
 - b. certificate of competence of the recipient;
 - c. a declaration that for electrical equipment, the electrical needs of the equipment will be set to the standard voltage of 240V/50Hz and for X-ray emitting equipment that it will be calibrated and inspected by a qualified Medical Physicist prior to shipment;
 - d. support letter from Federal Ministry of Health or Regional/City Administration Health Bureaus as appropriate; and
 - e. Performa invoice, where applicable
4. The agreement referred under sub-article (3) (a) of this article shall include the aim, source, beneficiary and location of beneficiary, amount, support and maintenance mechanism, sufficiency of spare parts and consumable items, responsible body, and monitoring and evaluation mechanism of the donation.
5. The letter mentioned under sub-article (3) (d) of this article shall clearly state if the issuing organization supports the donation, and mention or attach the type and amount of the intended donation.
6. The Authority shall give pre-import permit when the application fulfills the requirement provided under this directive. If the Authority rejects the application, it shall inform the applicant in writing by stating the reason for denial.
7. Unless renewed by the Authority, pre-import permit issued in accordance with this article shall be valid for only nine months.
8. While granting pre-import permit the Authority shall consider if the equipment is compatible with the level of the recipient.

8. Requirement at Port of Entry

1. Donated medical equipments shall have port clearance from the Authority before custom clearance.
2. Donated medical equipment at port of entry shall be accompanied by the following documentary evidences:

- a. valid pre-import permit;
 - b. donation certificate;
 - c. certificate of origin;
 - d. packing list;
 - e. commercial invoice, if applicable;
 - f. airway bill or bill of lading;
 - g. certificate of refurbishment for used equipment and
 - h. certificate of analysis for sterile medical equipment;
3. The certificate of refurbishment mentioned under sub-article (2) (g) of this article shall be issued by the manufacturer or certified company and shall state if the equipment is
 - a. tested, labeled and packed; and
 - b. replaced or repaired and the repair service that were performed on the equipment, and the source of the repair parts and provide an acceptance report for these parts;
 - c. calibrated it shall state and verify the operation of the equipment and the performance standard used to calibrate it; and
 - d. disinfected or decontaminated.
4. Donated medical equipment shall:
 - a. if applicable, be robust and fully operational as a full system or as a separate subsystem;
 - b. meet or exceed existing safety and performance specifications provided by the manufacturer, international or appropriate national organ;
 - c. include all essential parts, accessories and working materials;
 - d. have its label, user manual and other documents written in English or Amharic; and
 - e. be packed suitable for road, air or sea transport under tropical conditions.
5. For software operated equipment, the software shall be either preloaded and/or accompanied by the software package.
6. For electrical equipment, the electrical needs of the equipment shall be set to the standard voltage of 240V/50Hz and for X-ray emitting equipment that it shall be calibrated and inspected by a qualified Medical Physicist.

7. Damaged, outmoded, and redundant equipment for which spare parts and consumables are no longer available and/or equipment which is no longer supported by the manufacturer shall not be accepted.
8. Depending on its nature and type, the label of donated medical equipment shall at least include:
 - a. the name of the medical equipment;
 - b. model number or serial number;
 - c. manufacturing date;
 - d. life span or expectancy;
 - e. name and address of the manufacturer;
 - f. handling and storage requirement;
 - g. technical direction for use;
 - h. an indication, if applicable, that the medical equipment is intended to be used only for clinical or performance investigations before being supplied;
 - i. for a sterile medical equipment, the word “Sterile” and where appropriate, description of methods of re-sterilization;
 - j. if the device is a refurbished, an indication of the device as refurbished device;
 - k. if the device is intended for presentation or demonstration purposes only, it must be labeled as “for presentation or demonstration purposes only, not for use on human”;
 - l. if the device emits radiation for medical purpose, details of its nature, type and where appropriate, the intensity and distribution of this radiation;
 - m. if the device is to be installed with or connected to other medical device or equipment, or with dedicated software, in order to operate as required for its intended use, sufficient details of its characteristics to identify the correct device or equipment to use in order to obtain a safe combination;
 - n. if the device is an in vitro diagnostic medical device it must be labeled as “in vitro diagnostic” or “IVD”;
 - o. the intended purpose of the medical equipment, the intended user of the medical equipment, and the kind of patient on whom the medical equipment is intended to be used (if this information is not obvious).
9. The format, content and location of the information described under sub-article (4) of this article shall be appropriate for the medical equipment and its intended purpose.
10. Any number, letter or symbol, and any letter or number in a symbol, used in the label shall be legible.
11. Each donated medical equipments shall have accompanying user manual having detailed information on handling, installation, operation, maintenance, trouble shooting, precautions and other important information.
12. Donated medical equipment shall be transported, stored and handled in accordance with acceptable transportation, storage and handling requirements.

13. The location of labeling information provided under sub-article (4) of this article shall:
- a. Unless it is impracticable or inappropriate to do so, the information required to be provided with medical equipment shall be provided on the medical equipment itself.
 - b. If it is not practicable to comply with sub-article (13) (a) in relation to the provision of the information, the information shall be provided on the packaging used for the medical equipment, or in the case of medical equipment that are packaged together because individual packaging of the medical equipment for supply is not practicable, on the outer packaging used for the medical equipment.
 - c. If it is not practicable to comply with sub-article 13 (a) or (b) in relation to the provision of the information required, the information shall be provided on an insert supplied with the medical equipment.
 - d. If it is not practicable to comply with sub-article 13 (a), (b) or (c) the information shall be provided in a printed document or using other appropriate media.

9. Post entry Requirements

Donated medical equipments entered into the country in accordance with the above provisions shall be transported, stored, handled, distributed and used in accordance with applicable laws and standards of the Authority.

10. Rejection of Donation

Any donation which does not comply with the requirements prescribed under this directive shall be rejected.

Part Three

Miscellaneous Provisions

11. Reporting

The recipient shall report relevant information to the Authority including defects, adverse effect, problems related to quality and safety and other reportable cases related to the donated equipment.

12. Disposal

If donated medical equipments are found to be violative, the recipient shall dispose or return the product to the country of origin on its own expense.

13. Inapplicable Laws

No directive or practice shall, in so far as it is inconsistent with this directive, be applicable with respect to matters covered by this directive.

14. Effective Date

This directive shall enter into force on 13 August 2012.

Yehulu Denekew

Director General

Ethiopian Food, Medicine and Healthcare Administration and Control Authority



Ethiopian Food, Medicine and Healthcare Administration and Control Authority

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Annex I

Application Form

Medical Equipment Donation Request Form

1. Name of the applicant
2. Type of institution
 - a. Governmental
 - b. Non governmental
 - c. Private
3. Address of the institution
Region city.....sub city..... woreda.....
kebele..... email.....Tel
4. Person in charge of the application
 - a. Name
 - b. Qualification.....
 - c. Responsibility.....
5. Intended purpose of donation
 - a. Emergency
 - b. Development aid program
 - c. Other
6. Recipient for donation
 - a. Name
 - b. Address
Region city.....sub city..... woreda.....
Kebele..... e-mail.....Tel
 - c. Responsible person

Name..... Responsibility.....

7. Description of medical equipments

Item No.	Description of the Medical Equipment*	Unit	Quantity	Unit Price**	Total Price

* Description shall include Name, Brand, Batch or Model Number, Manufacture's Name, Date & Address, life span or expiry date, label language

** If the medical equipment is not a brand new, please specify estimated or book value.



Ethiopian Food, Medicine and Healthcare Administration and Control Authority

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Annex II

Pre-Import Permit for Donated Medical Equipment

Date.....

Ref. No.....

Name and address of recipient

Name and address of donor

The permission is granted to import the following medical equipments as per the Medical Equipment Donation Directive No. 8/2012 of the Authority

S.No	Item Description	Manufacturer	Country	Unit	Quantity	Unit Price	Total price

Mode of transportation _____

Port of arrival _____

This pre-import permit is valid only for none months from the date of its issuance
Upon arrival the consignment is subject to inspection to get import permit clearance