Ethiopian Food and Drug Authority

Guidelines for Medical Device Donations

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ACRONYMS

AC	Alternative current
DC	Direct Current
EFDA	Ethiopian Food and Drug Authority
eRIS	Electronic Regulatory Information System
GMP	Good Manufacturing Practice
ISO	International Organization for Standardization
IEC	International Electro-technical Commission
QMS	Quality management System
SOP	Standard Operating Procedure
USD	Single Use Device
IVD	In Vitro Diagnostic
COO	Certificate of Origin
COA	Certificate of Analysis

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1. INTRODUCTION

Medical devices constitute an essential components in the health care delivery system. These medical devices can be acquired through different acquisition modes including- purchasing, donation and others. Because of economic constraints, the health sectors of many developing countries including Ethiopia rely considerably on donations of the devices especially at the time of public health emergency. Article 25 sub-article 3 of the Food and Medicine Administration Proclamation 1112/2019 restricts the importation of any medical device unless authorization is granted by the Authority. A medical device to be donated might or might not be registered by the Authority. Article 20 sub-article 5 of the same proclamation gives the power to the Authority, in compelling circumstances, to grant a permit for the importation or use of unregistered medical device in which donation in emergency situation is one of such circumstances.

Donations of medical devices, in most cases, are made as a results of genuine desire to help, response to a request by recipient, desire to donate functional devices not necessarily required or needed by the donor. Donations of medical devices and IVDs can be very helpful, may improve the efficiency of health facilities, may save costs of purchasing new medical devices and may make some diagnoses or therapies accessible to patients, especially in resource-limited settings. Although most donations are made with good intentions, the outcomes are not always positive if the donations are not properly planned, coordinated and regulated. This guideline is therefore developed to put necessary principles and set requirements for donation of medical devices to be used in the Country.

Readers or users of this document can submit their feedbacks (specifically regarding the contents of this guidelines) to – Email: contactefda@efda.gov.et.

2. DEFINITIONS

Authority: - means Ethiopian Food and Drug Authority.

Donation:- means an act or instance of presenting medical device to recipients in emergency or as a part of development aid in non-emergency situation.

Donor:- means a governmental or nongovernmental organization or individual who voluntarily donates medical devices as a donation.

Recipient:- means a governmental, non-governmental or private health institution that voluntarily receives medical device as a donation.

Bill of Lading or Airway Bill – A document issued by a carrier that lists the medical devices being shipped and specifies the terms of their transport. Alternately – a legal document between the carrier of devices and the shipper that details the type, quantity, destination and receiver of the devices being shipped.

Certificate of Analysis (COA): A document signed by an authorized representative of a manufacturer describing specifications for and testing conditions and testing methods applied to a medical device and the results of the testing that confirms the device meets its product specification.

Certificate of Donation– This document is a customs declaration used to clearly state that the medical devices being transferred are being donated from the consigner to the consignee. The document is generated by the organization exporting the devices.

Certificate of Origin (COO): A document certifying that the medical devices in a shipment are wholly obtained, produced, manufactured or processed in a country.

3. SCOPE

The guideline is applicable to both persons and entities wishing to make medical devices (including IVDs) donations and the recipient of such donations.

4. OBJECTIVES

The main objective of this guideline is to provide guiding principles and set mandatory requirements for the donation of medical devices including In Vitro Diagnostic medical devices to be used in the Country.

5. PRINCIPLES OF GOOD PRACTICES FOR MEDICAL DEVICES DONATION

This guideline is based on four core underlying principles.

1. Donations of medical devices should benefit the recipient to the maximum extent possible. All donations should be based on an expressed need of the recipient. Unsolicited medical device donations are to be discouraged.

2. Donations should be given with due respect for the wishes and authority of the recipient, and in conformity with national government policies, relevant regulatory requirements and administrative arrangements of the country.

3. There should be no double standard in medical device quality and safety. If the quality and safety of a medical device is unacceptable in the donor country, it is also unacceptable as a donation.

4. There should be effective communication between the donor and the recipient, with all donations made according to a plan formulated by both parties.

6. REQUIREMENTS

6.1 Product related requirements

6.1.1. Safety, Specifications and Standards

Medical device should meet or exceed existing safety and performance specifications provided by the manufacturer, and where applicable, they should meet standards promulgated by international bodies such as International Organization for Standardization (ISO), International Electro-technical Commission (IEC) and standards accepted by the national government of Ethiopia. Medical device that has not been approved by the appropriate regulatory agency of the donor country should not be donated. Medical device that is the subject of manufacturer recalls or hazard alerts should be updated to the new requirements or not be donated.

Donated medical device should:

a) if applicable, be robust and fully operational as a full system and as a separate subsystem;

b) meet or exceed existing safety and performance specifications provided by the manufacturer, international or the Authority;

c) include all essential parts, accessories and working materials;

d) have its label, user manual and other documents written in English or Amharic. The labeling information shall be as per the Authority's Guideline for Medical Device Labeling.

e) If the medical device to be donated incorporate software, the software should have English language as one of its operation languages.

6.1.2. Obsolescence

Obsolete medical device or medical device for which replacement parts are unavailable should not be donated.

6.1.3. Shelf life and Useful life

For a donated medical device whose shelf-life is determined and labeled by the manufacturer, the device's remaining shelf life at the time of arrival should:-

a) Not be less than 30 months for a medical device whose shelf life is more than 48 months.
b) Not be less than 24 months for a medical device whose shelf life is from 36 to 48 months.
c) Not be less than 15 months for a medical device whose shelf life is from 24 to 36 months.
d) Not be less than 12 months for a medical device whose shelf life is less than 24 months.

If the device's determined shelf life is 12 months or less, the remaining shelf-life at the time of arrival should not be less than half of the total shelf-life determined by the manufacturer.

For a medical device whose useful life ('for how long the device can be used') is determined and labeled by the manufacturer and the device to be donated has been previously used before the donation, the remaining useful life at the time of arrival at the port of entry should not be less than one third of the total useful life determined by the Manufacturer.

6.1.4. Technology Appropriateness

The preferred desirable characteristics in donated medical device are:

- Simplicity of operation.
- Minimal number of accessories required.
- Availability of necessary operating supplies (particularly disposable) in the recipient country, at affordable cost.
- Standardization with other medical devices available in the local market.
- Low energy consumption.
- Does not use environmentally hazardous substances.

- Ease of maintenance.
- Tolerance to hostile electrical and physical environment.

6.1.5. Refurbished devices

An establishment responsible for refurbishing of medical devices are responsible for restoring device to its original working condition, and are therefore subject to general principles of liability. An establishment is required to follow the Medical device Good Manufacturing Practices (GMP) established by the authority during refurbishing of medical device. Such device is expected to be restored to the manufacturer's original specifications.

The refurbished medical device should equal, or sometimes surpass, the original device manufacturer's safety and performance specifications. Fully refurbished device mean that a device has been completely rebuilt / made as new from used devices and is assigned a new useful life. It should be considered as a new device if a new intended purpose was assigned.

6.1.6. Single Use Devices (SUDs)

Some companies engage in the practice of reprocessing devices that are labeled or intended for single use. A reprocessed medical device refers to a used medical device that is meant for single use but has been cleaned or disinfected/sterilized or reprocessed and repacked for another use. SUDs can be donated only if they have never been used or reprocessed.

6.1.7. Special requirements

Any special requirements for proper use of the medical devices should be identified and communicated to the recipient. These include, but not limited to:

- Infrastructure requirement (dimensions, height)
- air or water cooling
- water quality
- medical gases

- mechanical lay-out, radiation or acoustic shielding requirements
- specialized software required to install, operate, or maintain medical device

For software operated device, the software should be either preloaded and/or accompanied by the software package. For electrical device, the electrical needs of the device should be set to the standard voltage of 220V/50Hz for single phase devices, 380V/50Hz for three phase medical devices and for X-ray emitting device, it shall be calibrated and inspected by a qualified personnel.

6.1.8. Registration status by the Authority

Where the device to be donated has been registered by EFDA, the recipient of the donated medical device is required to liaise with the Company that holds the market authorization issued by the Authority. This is for the purposes of monitoring the safety of the device. Where the device is not registered in Ethiopia, importation of the donated product is permitted by the Authority if the pre-import requirements provided in this guidelines are complied. This is to enable the EFDA to monitor the safety of the medical device while being used in the country and as applicable to conduct testing of the device.

6.2 Application Requirements for the donations

6.2.1. Pre-import Permit Application

1. An applicant who wants to import or receive medical device as a donation shall have a pre-import permit from the Authority.

2. An applicant who seeks pre-import permit shall submit an application through the electronic Regulatory Information System (eRIS) of the Authority. The required documents during application includes:

    a) Application letter

    b) an agreement entered into between the donor and recipient;

    c) Certificate of Competence of recipient or license issued by the responsible body. For UN agencies, support letter from Ministry of Foreign Affairs of Ethiopia.

d) Supporting letter from Federal Ministry of Health or Regional/City Administration Health Bureaus as appropriate;

e) Medical Device Quality Management System (QMS) certificate (ISO 13485), as appropriate

f) Proforma Invoice

g) Donation certificate

h) Certificate of Origin

i) Certificate of analysis, If applicable

j) Declaration that (for electrical equipment) the electrical needs of the equipment will be set to the standard voltage of 220V/50Hz for single phase devices, 380V/50Hz for three phase medical devices and for X-ray emitting equipment that it will be calibrated and inspected by a qualified personnel prior to shipment.

k) A checklist completed by the donor containing all available sub-systems, components, accessories, and supplies.

l) Operating and service manuals with part lists (critical to the usability of the donated device

m) For used medical devices, the year of manufacture, duration of previous use and useful life (both in years) determined by manufacturer.

n) Refurbishment certificate issued by a licensed refurbisher.

3. The agreement referred under 2(b) of this section 6.2.1 shall include the aim, source, beneficiary and location of beneficiary, amount of device, support and maintenance mechanism, sufficiency of spare parts, accessories and consumable items, responsible body for monitoring the safety and performance of device, and monitoring and evaluation mechanism of the donation.

4. The support letter mentioned under 2(c & d) of this section 6.2.1 shall clearly state if the issuing organization support the donation, and mention or attach the type and amount of the intended donation. The issuing organization should also clearly state that the applicant is legal entity and has valid license.

5. The Authority give pre-import permit when the application fulfills the requirement provided in this guideline. If the Authority rejects the application, the applicant is informed the reason for denial through eRIS system.

6. The issued pre-import permit in accordance with this guideline's requirements shall be valid for only one year.

6.2.2. Requirements at Port of Entry

Donated medical devices shall have port clearance from the Authority just like other imported devices acquired through other modes of acquisition (eg. purchase).

Donated medical devices at port of entry shall be accompanied by the following documents 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 and refurbished medical device and

h) certificate of analysis, if applicable;

i) Operating and service manuals with part lists.

For refurbished medical device, the product label should have the date of refurbishment, name and address of the refurbisher.

The certificate of refurbishment mentioned in this document should be issued by the manufacturer or a licensed refurbishing company and should state if the medical device is

a) tested, labeled and packed; and

b) replaced or repaired and the repair service that were performed on the medical device, and the source of the repair parts and provide an acceptance report for these parts;

c) calibrated; it should state and verify the operation of the medical device and the performance standard used to calibrate it; and

d) disinfected or decontaminated.

6.2.3. Fees and Sampling

All fees in connection with the donation of medical devices should be as specified in the current fee Rate of service fees regulation of the Authority.

EFDA may take samples for consignment testing from the consignment at port of entry as per the sampling Standard Operating Procedure (SOP) of the Authority.

6.2.4. Applicant

An application for processing of medical device donations can be made by the donor or recipient. Such an applicant should be responsible for the medical device imported and all issues relating to the device, including any information accompanying the device.

A non-resident applicant should be required to appoint a recipient with the requisite mandate to represent the said applicant.

7. RESPONSIBILITIES

7.1 Responsibilities of Recipients

a) Standardizing medical device

Equipping a health institutions is more than simply obtaining the device. Maintenance is vital, and maintaining a vast array of different medical device can be problematic.

Important issues to consider with regard to standardization include:

- **Staff experience, and training** required for installation, operation, and maintenance. Consider both the clinical staff and the technical service staff required to operate the device.

- Location for the device including site accessibility and the space available.

- **Climatic and environmental conditions**, such as heat (temperature), humidity, dust, ventilation, etc.

- **Utilities**: power supply (electric, gas, generator, fossil fuel, wood fuel, solar, windmill, biogas, etc.), reliability of supply (fluctuating power, interruptions, rationing, etc.), type of power (voltage, frequency, phase, AC/DC); type of water (polluted, salty, hard, soft, etc.) and the means of delivery (piped, stored, well, river, rain, etc.).

- **Support services** required for operation, procedures, and clinical use of the device. Keep in mind that modern device may offer a wide variety of operational modes and may simplify the performance of certain procedures but it is often very expensive, and may need both health specialists and a manufactures' service network for maintenance and repair. When these are available, spare parts and special maintenance tools that are costly may be required. Sophisticated device often has very sensitive parts.

- **Maintenance costs:** in terms of spare parts, downtime during normal servicing and level of expertise of technical staff required.

- **Availability of consumables:** Some device may require consumables which are not available locally, for example, special papers, films, filters, etc. These are recurrent cost items and their availability must be assured.

- **Other specific requirements related to the device**. For example, whether a new addition will conform with existing device, whether a cold room is required for computerized device, or especially solid walls for x-ray machines, or a boiler for autoclaves, or power stabilizers for electronic device etc.

- **Experience of others with similar device, brands, or sources.** The recipient should check the previous safety, performance and suitability status of the existing devices similar to the one to be donated (similarity of the manufacturer, of brand and of model).

The aim of standardize devices is providing criteria to help define medical device that is technologically and clinically appropriate to the intended use.

b) Involving technical departments

In ordering device or receiving donation, the technical personnel must be involved. As experts, they will consider and advise upon:

- All aspects of the requirements for installation, operation, and maintenance.
- Essential spare parts and other special requirements, their availability, and costs
- Availability of technical personnel and level of training required
- Estimated lifespan of the device based on the model, year of manufacture and whether it is new or reconditioned.
- Appropriateness of the device in terms of running costs and design.
- If a financial contribution may be more appropriate than a donation of medical devices.

c) Specify clearly items to accompany the medical device

All medical devices must be provided with a full set of technical documents. That is, documentation for installation, for user operation, for repair and maintenance (manuals), a list of

spare parts (containing- part name and number, and full name and address of the manufacturer), accessories and technical data (eg. performance data). The language in which documents should be made available in English.

All medical devices must be accompanied by a reasonable quantity of spare parts and consumable items. This should take into account the "lead period" (i.e. period between placing an order and receipt of spare parts). If the lead period is two years, then spare parts and consumables are needed to cover that period.

All new medical device must be accompanied by documents of warranty (guarantee).

d) Make a check-list

Compiling a check-list will include consideration of all issues discussed above. It will ensure that the donor receives all the information required in order to make an appropriate donation.

e) Communicate alternative preferences

If a financial contribution to allow local or regional purchase would be more appropriate, cheaper or easier, state this information clearly. Issues on which the donor is unable to comply can then be discussed. The solution should be understood and agreed upon by both parties. As a result, the donors will not substitute items believing that such alternatives would be equally suitable. If donations of device that are not needed are received, inform the donor immediately.

7.2 Responsibilities of Donors

Donated medical devices will only be useful if it is properly installed, operated, maintained, and appropriately used. To ensure the donated medical device is useful, the donor has the responsibilities of:

a) Communicate with the recipient

Before supplying any medical device, request for a comprehensive description of the device required by the recipient (including their check-list). Ensure that the conditions that cannot be fulfilled are communicated to the recipient. An agreement on all conditions should be reached

before shipping the device. This ensures that the medical device supplied is clinically, economically, and technologically appropriate.

b) Supply fully functional medical device

Medical devices whether new or refurbished, should be tested and all essential parts, accessories and working materials included before shipment. A basic list of all components must be provided to the recipient. Second-hand device should be fully reconditioned or refurbished. It should be established that the manufacturer continues to produce spare parts, and the "life expectancy" of the device should be indicated.

Non-functional, outmoded, and redundant device for which spare parts and consumables are no longer available, or device which is no longer supported by the manufacturer should not be donated.

c) Supply all technical documents.

These include all installation, operation, maintenance, and repair manuals. It is particularly important to include technical diagrams as the symbols used are usually international. The technical documents should be supplied in the language understandable by users and recipient (English).

d) Supply an initial requirement of consumables and spare parts

Recipients often face lengthy and complicated procurement procedures. The Authority recommends that the medical device be supplied with an initial consignment of consumables and spare parts expected to last at least two years (or as requested).

e) Ensure proper packaging

The consignment is likely to endure long periods during transport such as in ships, aeroplanes and vehicles. The packaging must therefore be strong and sturdy to withstand rough handling and to minimize damage during transportation. It should also:

- Include a clear packing list identifying all components

- Be of appropriate size that can be handled using simple mechanical devices and manual labour.

f) Supply shipping documents promptly

Consignments may remain longer at port of entry, facing possible damage and accumulating demurrage charges (penalty for delayed action) due to late submission of shipping documents.

g) Offer technical assistance.

Where possible, promote, recommend and provide training (including onsite training) for the use and maintenance of the medical device.

h) Understand import regulations of Ethiopia.

The donor should understand the governing national regulation including applicable directives and this guideline while planning for donation of medical devices. These includes any restriction on who can receive donations, and which indicate taxes and other charges. It is also important to assess the ability of the recipient to pay the accompanying local costs.

8. REFERENCES

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