FOOD AND DRUGS AUTHORITY

GUIDELINE FOR DONATION OF

MEDICAL DEVICES

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1.0 Introduction

Medical Devices constitute essential components in the delivery of effective health care. The safety, quality and performance of medical devices are thus of importance in the regulatory framework. Experts have estimated the lifecycle of a medical device to be between 18 and 24 months – within this period, an improved version of the device would have been produced.

Consequently, those who have the means are able to acquire the newer versions making it imperative for the older versions to be released to those who, for obvious reasons, would need them. Such devices are either donated or sold. They are given away either in the same state in which they are, or refurbished or reprocessed.

To ensure that these medical devices are safe, of the required quality and performance standards, regulatory oversight is important. Most of these medical devices are donated to recipients in developing countries.

In pursuance of Section 148 of the Public Health Act, 2012, Act 851, these Guidelines are hereby promulgated for information, guidance and strict compliance by all concerned on the procedure and requirements for the donation of medical devices in Ghana. These guidelines are applicable to all medical devices for use in humans as well as medical devices for veterinary use, where applicable.

These guidelines must be read and used in conjunction with the enabling legislation, the Public Health Act, 2012, Act 851, Part 7, the current version of the FDA Guideline for Registration of Medical Devices, as well as any other relevant Guidelines and Regulations issued by the Food and Drugs Authority.

2.0 Glossary

In these Guidelines, unless the context otherwise requires, the following terms have the assigned meanings:

Authority: The Food and Drugs Authority, Ghana.

Manufacture: Includes all operations involved in the production, preparation, processing, compounding, formulating, filling, refining, transformation, packing, packaging, repackaging and labelling of medical devices.

Manufacturer: Means any natural or legal person1 with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s).

Refurbisher: a person/company that restores a device to a condition of safety and effectiveness that is comparable to when new. This includes reconditioning, repair, installation of certain software/hardware updates that do not change the intended use of the original device, and replacement of worn parts.

Medical Device or Devices: Refer to an instrument, apparatus, implement, medical equipment, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, which is:

(a) Recognized in the Official National Formulary, or Pharmacopoeia or any supplement to them;
(b) Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals or;

(c) Intended to affect the structure or any function of the body of man or other animals and which does not achieve any of its principal intended purposes through chemical action within the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principle intended purposes.

ACRONYMS

***GSA*:** Ghana Standards Authority

***IEC*:** International Electrotechnical Commission

***SUD*:** Single Use Devices

3.0 REQUIREMENTS

3.1 General

3.1.1 Principles of Good Donation

The four underlying principles, which form the core of *Good Donation Practice,* are: 1) Medical device donations should benefit the recipient to the maximum extent possible. 2) Donations should be given with due respect for the wishes and authority of the recipient, and in conformity with government policies and administrative arrangements of the recipient country.

3) There should be no double standard in quality. If the quality of an item 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.

3.1.2 General Quality

- The donor should ensure that donated medical device is fully operational at the system and sub-system levels, and that all essential accessories and supplies are available.

Documentation

- A checklist completed by the donor to ensure that all sub-systems, components, accessories, and supplies (for initial operations) are included. Checklists are often found in operating manuals produced by the manufacturer or prepared by the former operators, in the case of previously used equipment.
- Operating and service manuals with part lists (critical to the usability of the donated equipment).

3.1.3 Safety, Specifications and Standards

- Equipment 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 Electrotechnical Commission (IEC) and standards approved by Ghana Standards Authority (GSA).
- Equipment that has not been approved by the appropriate regulatory agency of the donor country should not be donated.
- Equipment that is the subject of manufacturer recalls or hazard alerts should be updated to the new requirements or not be donated.
- Equipment that has non-functional sub-systems may be donated provided that those sub-systems are clearly identified and labelled.

3.1.4 Obsolescence

Obsolete equipment or equipment for which replacement parts are unavailable should be donated only if they are destined "for parts only", and so designated.

3.1.5 Appropriate Technology

Preferred desirable characteristics in donated equipment:

- 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 equipment in the locale.

- Low energy consumption.
- Does not use environmentally hazardous substances.
- Ease of maintenance.
- Tolerance to hostile electrical and physical environment.

3.1.6 Additional requirements

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

- Infrastructure requirement (dimensions, height)
- air or water cooling
- electrical power
- water quality
- Medical gases
- mechanical lay-out, radiation or acoustic shielding requirements
- specialized software required to install, operate, or maintain equipment

3.1.7 Registration

3.1.7.1 Where the device to be donated has been registered in Ghana by the FDA, the recipient of the donated item would be required to liaise with the Company that holds the market authorization in Ghana. This would be for the purposes of monitoring the safety of the device.

3.1.7.2 Where the device is not registered in the country, a first time donation would be permitted without the fulfillment of the registration requirement. However, the recipient and or donor must notify FDA before donation arrives. This is to enable the FDA monitor the safety of the medical device.

3.1.7.3 Where a second donation of a medical device is to be made, the donation would be permitted only after the product has been duly registered. The appropriate regulatory sanctions and penalties would be applied in default.

3.1.8 Fees

All fees in connection with the donation of medical devices would be as specified in the current FDA Fee Schedule.

3.1.9 Sampling

Sampling of the devices would be in conformity with the FDA sampling schedule.

3.1.10 Letter

All applications for processing of medical device donations shall be made by submitting a letter addressed to:

The Chief Executive Officer, Food and Drugs Authority, P. O. Box CT 2783, Cantonments, Accra

3.1.11 Applicant

An application for processing of medical device donations can be made by a manufacturer, the donor, or by an importer of the medical devices. Such an applicant would be responsible for the product and all issues relating to the product, including any information accompanying the product.

A non-resident applicant would be required to appoint a local agent with the requisite mandate to represent the said applicant. For donation of medical devices, the local agent may be the recipient of the donated devices. The agent would be required to produce the relevant documentation including, but not limited to, a power of attorney or any other documentation, affirming his/her appointment as an agent.

3.1.12 Local Agent

A local agent is a natural person resident in Ghana or a corporate body registered in Ghana, with the relevant mandate from the applicant, to act on the applicant's behalf as regards matters relating to the registration of a medical device(s) in Ghana. The Local Agent would, among other things:

3.1.12.1 Monitor the device and appropriately inform the Authority of any relevant issue relating to the device, including any serious manufacturing defects with the potential to endanger the safety and/or health of the patient, operator or any other person, or public health.

3.1.12.2 Facilitate communication between the applicant and the Authority on matters relating to the product.

3.1.12.3 Handle device recalls.

3.1.12.4 Provide technical support and services to users of the device(s).

3.2 Specific Requirements

3.2.1 Used Equipment

Normally these are medical devices removed from service in hospitals in well-resourced environment, and donated to hospitals in less-resourced environment. Most of these never become operational. Where they are operational, however, most of these never work for any significant length of time. Again, in situations where they work, they can rarely be supported without adequate local arrangements for the necessary training, maintenance, spare parts, and user's and service manuals.

Second-hand medical devices are those which are already on the market and have been 'pre-owned' and used and that are subsequently 'sold on' or donated for the same continued use.

3.2.1.1 Requirements for Used Equipment

- Document the source of all purchased equipment.
- Document the components that were replaced in, and the repair services that were performed on the equipment. (Maintenance and service history of the medical device)
  - Submit and include the following:

    a. User Manual (Service and Maintenance)
    b. Installation manual

c. Spare parts
d. Training
e. Consumables
f. Accessories
g. Decommissioning report

- Label the equipment with the re-manufacturer's name.
- Maintain a customer complaint file and document the actions that were taken to resolve customer complaints.
- An Engineer's Report stating the status of the device, the reason for decommissioning the equipment and the functional status.

3.2.2 Refurbished Equipment

Refurbishers of medical devices are responsible for restoring equipment to its original working condition, and are therefore subject to general principles of liability. Refurbishers are required to follow the Good Manufacturing Practices (GMP) established by their national authorities for manufacturers of medical devices.

Such devices are expected to be restored to the manufacturer's original specifications. The refurbished equipment should equal, or sometimes surpass, the original equipment manufacturer's specifications. 'Fully refurbished' is considered to mean that a device has been completely rebuilt / made as new from used devices and is assigned a new 'useful life'. It would also be considered as a new device if a new intended purpose was assigned.

3.2.2.1 Requirements for Refurbished Equipment

- Document the source of all purchased equipment.
- Provide the requisite certificate of analysis.
- Attach the GMP certificate of the manufacturer.
- Label the equipment with the re-manufacturer's name and indicate that the equipment has been refurbished.
- Verify and document the operation of the equipment and the performance standards used to calibrate it (Operational and user manual).

- The refurbisher’s manufacturing license and a Certificate of Free Sale.

3.2.3 Single Use Devices (SUDs)

Some institutions 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, disinfected/sterilized and repacked for another use.

3.2.3.1 Requirements for Single Use Devices (SUDs)

- SUD can be donated only if they have never been used or reprocessed
- Must have a shelf life of not less than six months remaining upon arrival at the port
- Document the source of all purchased equipment.
- Verify and document the operation of the equipment and the performance standards used to calibrate it.
- Provide the requisite certificate of analysis.
- Attach the GMP certificate of the manufacturer where applicable
- Attach the manufacturer’s license and a Certificate of Free Sale.
- Labeling

i. SUDs must be appropriately labelled ii. Repackaged SUDs must prominently and conspicuously bear the statements:

- "Repackaged device for single use.”
- “Repackaged by [insert the name of the manufacturer that repackaged the device].

iii. Label the equipment with the packager’s name.

4.0 Timelines

A minimum period of 6 (six) months is to be allowed for the completion of the process.

5.0 Sanctions

A person who contravenes these Guidelines or sections thereof is liable to regulatory sanctions per Sections 119 and 132, Part 7, Act 851, the Public Health Act, 2012 which shall be imposed by the Authority. These sanctions may include, but not limited to, any of the following:

5.1 Suspension of the processing of a pending application for donation.

5.2 Suspension of the processing of a pending import license application.

5.3 Cancelation of an import license

5.4 Payment of administrative charges as per the current Fees and Charges (Amendment) Instrument.

6.0 Penalties

In line with the provisions of Section 129, Part 7, Act 851, the Public Health Act, 2012, a person who contravenes these Guidelines commits an offence and is liable on summary conviction to a fine of

6.1 not less than seven thousand five hundred (7,500) penalty units and not more than Fifteen thousand penalty units (15,000), or

6.2 to a term of imprisonment of not less than fifteen years and not more than twenty-five years, or

6.3 to both.