

TANZANIA FOOD AND DRUGS AUTHORITY



**GUIDELINES FOR GOOD DISTRIBUTION PRACTICES OF
MEDICAL DEVICES**

DRAFT

June, 2010

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Abbreviations

EEFO	-	Earliest-Expiry-First-Out
GDP	-	Good Distribution Practice
FIFO	-	First-In-First-Out
GMP	-	Good Manufacturing Practices
SOP	-	Standard Operating Procedure
TFDA	-	Tanzania Food and Drugs Authority
TFDCA	-	Tanzania Food, Drugs and Cosmetic Act of 2003

Acknowledgements

We would like to thank TFDA staff who contributed for successful development of this guideline. Acknowledgement is particularly extended to Mr. M. A. Fimbo, Mr. A. Khea, Mr. E. Alphonse, Ms. Agnes Kijo, Mr. A. Bitegeko, Ms. R. Mariki, Ms. K. Mwamwitwa, Ms. S. Mkumbwa and Mr. B. Simon.

We would also like to thank Health Science Authority (HSA) of Singapore for making their guidelines available for reference.

Special thanks are also extended to TFDA esteemed stakeholders; the dealers in medical devices who discussed the draft guideline and gave commendable inputs for improving the guideline.

Last but not the least, TFDA Management is acknowledged for constructive comments and inputs during deliberation and approval of the guideline.

M. A. Fimbo
Acting Director, Medicines and Cosmetics
Tanzania Food and Drugs Authority

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In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

Foreword

The Tanzania Food and Drugs Authority (TFDA) were established under the Tanzania Food, Drugs and Cosmetics Act, 2003 to regulate among other things importation, manufacture and distribution of medical devices.

Distribution activities which involve importation, transportation, receiving, handling, storage, recording and record keeping, dispatching and delivery to consumers are an important part of the lifecycle of the device and can greatly influence the quality and performance of the device.

This guideline sets out appropriate control for the effective, efficient and safe handling, storage, transportation, distribution and post market vigilance of medical devices. For every medical device, a number of these controls are applicable. It is however, recognized that some of these control are not applicable in certain situation. The control should be adapted to meet individual devices where necessary. Meeting requirements stipulated in this guideline does not exempt any person from fulfilling other legal obligations related to medical device(s).

Dealers of medical devices are encouraged to familiarize with this guideline as it intends to provide guidance on the best practices which if implemented will ensure the quality, safety and performance of devices is maintained throughout the supply chain.

H.B. Sillo
Acting Director General
Tanzania Food and Drugs Authority

Introduction

This guideline has been developed to provide general guidance for implementation of Good Distribution Practice for medical devices in Tanzania.

Good Distribution Practice is part of quality assurance system that ensures safety; quality and integrity of medical devices are maintained through adequate control of the numerous activities which occur within the distribution chain. These activities aim at ensuring that medical devices are of good quality when delivered to their customers and that when problem arise, device product tracking and corrective action are performed promptly and efficiently.

In developing the guideline, reference was made from the following documents:-

- (a) Guidelines for Good Distribution Practices of Medicines in Tanzania, First edition, September, 2009 of Tanzania Food and Drugs Authority.
- (b) TS-01-R1: Good Distribution Practice for Medical Devices in Singapore – Requirements.

The guideline provides guidance on personnel, premises and facilities, stock handling and stock control, disposal of device products, documentation, handling of device complaints, recall of device(s), handling of returned devices, handling of counterfeit, adulterated, unwholesome and tampered device(s) and contact activities.

The guideline is applicable to persons who import and supply by whole sale medical devices in Tanzania.

Applicants are also requested to read the guideline together with Guideline for Application of Permits to Deal with Business of Medical Devices, the Tanzania Food, Drugs and Cosmetics Act, 2003 and its amendments and regulations made there under.

Definition of terms

In the context of this guideline, the following terms shall be defined as follows:

Act

Means Tanzania Food, Drugs and Cosmetics Act, 2003.

Authority

Means Tanzania Food and Drugs Authority.

Batch Number

Means a distinctive combination of numbers and/or letters which uniquely identifies a batch on the label.

Contamination

Means the undesired introduction of a chemical or microbiological nature, or foreign matter into a medical device during handling, packaging, or repackaging, storage or transport.

Distribution

Means supply or movement of devices from the premises of the manufacturer of such products, or another central point, to the end-user thereof, or to an intermediate point by means of various transport methods, via various storage and/or health establishments.

Distributor

Means an entity or person appropriately authorized or entitled to distribute medical devices in accordance with the provisions of the Act or any other law in force.

Expiry date

Means the date given on the individual container (usually on the label) of a device product up to including which the product is expected to remain within specifications, if stored correctly.

EEFO (Earliest-Expiry-First-Out)

Means a distribution procedure that ensures the stock with the earliest expiry date is distributed and/or used before an identical stock item with a later expiry date is distributed.

FIFO (First-In-First-Out)

Means a distribution procedure to ensure that the oldest stock is distributed and/or utilized before a newer and identical stock item is distributed and/ or utilized

Good Distribution Practice (GDP)

Means part of quality assurance that ensures the quality of devices is maintained through adequate control throughout the numerous activities which occur during the distribution process.

Labeling / information supplied by the manufacturer

Written, printed or graphic matter affixed to a medical device or any of its containers or wrappers, or, accompanying a medical device, related to identification, technical description, and use of the medical device, but excluding shipping documents.

Medical Device(s) or Device(s)

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.

Premise

Means a location that is used for activities dealing with medical devices, including storage and manufacture.

Quarantine

The status of products being isolated while a decision is awaited on their fate

Recall

Is a process of withdrawing or removing a device from distribution chain because of defects or complaints of serious adverse event to the device.

Standard Operating Procedure (SOP)

An approved, written procedure giving instructions for performing given operations.

GOOD DISTRIBUTION PRACTICE

PRINCIPLES AND REQUIREMENTS

1. PERSONNEL

- 1.1 Key personnel in charge of warehousing operations should possess appropriate knowledge and experience, and where applicable, the relevant professional and technical qualifications for the tasks assigned to them.
- 1.2 All personnel should receive proper training in relation to GDP, current medical device legislations & regulations, operating procedures and safety issues, in accordance with a written training programme. Special training should be provided for personnel dealing with certain categories of substances/materials such as chemicals, biological, radiation emitting or energy source components and products. Training records should be maintained.

2. PREMISES AND FACILITIES

2.1 Areas & General Description

- 2.1.1 Premises must have a permanent address and be located at a site approved by TFDA.
- 2.1.2 The storage of device products should be carried out in buildings or parts of buildings that have been built for, or adapted to this purpose.
- 2.1.3 Buildings should protect device products from contamination and deterioration, including protection from excessive heat or undue exposure to direct sunlight.
- 2.1.4 Buildings should have sufficient security to prevent unauthorized access and misappropriation of the device products.
- 2.1.5 Premises should be constructed, serviced and maintained regularly to protect stored device products, from all potentially harmful influences such as undue variations of temperature and humidity.
- 2.1.6 There should be adequate storage areas, and where applicable, physically separated zones for the orderly segregation of device products.
- 2.1.7 The storage areas should have adequate lighting and ventilation.

2.2 Cleanliness

2.2.1 The storage areas should be dry, clean and free of accumulated dust and waste.

2.3 Storage of device products

2.3.1 Device products should be stored off the ground and suitably spaced to permit cleaning and inspection. Pallets should be well maintained and kept in a good state of cleanliness.

2.3.2 There should be designated areas for quarantined, saleable stock, expired, rejected/damaged, recalled and returned device products. Alternative means of segregation should be considered if proven to prevent mix-up

2.3.3 Appropriate and suitable storage conditions should be provided for hazardous, sensitive and dangerous materials such as combustible liquids and solids, pressurized gases, highly toxic and radioactive substances.

2.3.4 Adequate precautions should be taken for spillage or breakage, attack by microorganisms, contamination and cross-contamination.

2.3.5 Device products requiring special storage conditions (e.g. temperature and/or humidity) should be placed in separate areas constructed and equipped to provide the desired conditions. A list of such device products should be maintained and the device products properly identified.

2.3.6 Where controlled environmental storage conditions are required, these conditions should be continuously monitored and documented. Appropriate actions, on the premise, equipment and/or materials should be taken when the storage conditions are not met. As far as possible, the actual storage temperature should be expressed quantitatively. Where the storage temperature is not expressed quantitatively or stated (in terms of a range) on the labels of the registered device product, the following definitions, given in the table below, should be used as guidance:

On the label	Guidance value
Freezer	The temperature is thermostatically controlled between -20°C and -10°C
Refrigerator	The temperature is thermostatically controlled between 2°C and 8°C
Cold place	The temperature does not exceed 8°C
Cool place	The temperature is between 8°C and 15°C
Room temperature	The temperature is between 15°C and 30°C
Warm	The temperature is between 30°C and 40°C

Excessive heat	The temperature is above 40°C
Do not store over 30°C	The temperature is between 2°C and 30°C
Do not store over 25°C	The temperature is between 2°C and 25°C
Do not store over 15°C	The temperature is between 2°C and 15°C
Do not store over 8°C	The temperature is between 2°C and 8°C
Do not store below 8°C	The temperature is between 8°C and 25°C

Whereas storage conditions stated on the label mean the following:

On the label	Guidance value
Protect from moisture	No more than 60% relative humidity in normal storage conditions; to be provided to the user in a moisture-resistant container
Protect from light	To be provided to the user in a light resistant container

2.3.7 Device(s) products in cartons/bulk packs should be adequately labeled for identification.

2.4 Pest Control

2.4.1 The storage area should be designed and equipped to prevent the entry of insects, rodents and other pests/animals

2.4.2 There should be a pest control programme to identify and prevent pest infestation. Appropriate records should be kept for these purposes.

3. STOCK HANDLING AND STOCK CONTROL

3.1 Receiving and Handling Device Products

3.1.1 Upon receipt, each incoming delivery should be checked against the relevant documentation and physically verified by label description, type and quantity, against the relevant purchase order information. The type and nature of checks should be stated in a written procedure.

3.1.2 All containers should be carefully inspected for tampering, contamination and damage and if necessary the suspected container or the entire delivery should be quarantined or set aside for further investigation.

3.1.3 Records should be retained for each delivery. They should include the description of the goods, quality, quantity, supplier, supplier's batch number, the date of receipt and assigned batch number. Where current regulations state a period for retention of records, this should be followed.

3.1.4 Secure measures should be taken to ensure that rejected device products cannot be used and they should be stored separately from other device products while awaiting destruction or return to the supplier. The measures adopted should possess adequate safeguards to prevent uncontrolled or unsatisfactory device products from being used or released.

3.2 Stock Rotation and Control

3.2.1 Comprehensive records should be maintained showing all receipts and issues of device products according to batch number.

3.2.2 Periodic stock reconciliation should be performed comparing the actual and recorded device products quantity. In any case, this should be performed when each batch is totally exhausted. All significant stock discrepancies should be subjected to investigation to check for inadvertent mix-ups and wrong issues.

3.2.3 A system should be in place to ensure that device products due to expire first are sold and/or distributed first (Earliest-Expiry-First Out, EEFO). Where no expiry dates exist for the device products, FIFO (First-In-First-Out) should be applied. Deviations should, however, be permitted in exceptional cases where such deviation is temporary and appropriate.

3.2.4 Device products with broken seals, damaged packaging or suspected tampering/contamination must not be sold or supplied.

3.2.5 Device products bearing an expiry date must not be received or supplied close to or after this date such that this date is likely to occur before the consumer uses the device products.

3.2.6 All labels and containers of device products should not be altered, tampered or changed. The legislations relating to labels and containers should be adhered to at times.

3.3 Transportation and Deliveries to Customers

3.3.1 There should be adequate provision for the security, storage condition and protection of the quality of device products during all transportation. The transport process should not affect the integrity and quality of the device products.

3.3.2 Device products should be transported in such a way that:-

- Their identification is not lost;
- They do not contaminate, and are not contaminated by, other device products or materials/substances;

- Adequate precautions are taken against spillage, breakage or theft;
 - They are secure and not subjected to unacceptable degrees of heat, cold, light, moisture or other adverse influence, or to attack by microorganisms and pests.
- 3.3.3 Device products requiring controlled temperature storage should be transported by appropriate or specialized means. Special care should be exercised when using dry ice during transportation. Device products should not come into contact with dry ice as this may cause freezing of the device products.
- 3.3.4 The use of device products to monitor temperature during delivery is recommended. Such records should be reviewed.
- 3.3.5 Vehicles used should be adapted and maintained to suit the operations to be carried out. Vehicles should not be used as a store for device products.

4. DISPOSAL OF DEVICE(S)

- 4.1 Device products for disposal should be kept in a clearly separated area so that they cannot be sold in error or contaminate other device products.
- 4.2 Disposal of device products can be done after getting a written approval from TFDA and in line with directives issued by the Authority.

5. DOCUMENTATION

5.1 Types of Documentation

- 5.1.1 The documentation system should include the relevant SOPs and records, specifications of device products, and legal records. Any computerized document or format should comply with the current legislative requirements and/or international practices for electronic documentation and computerized systems. Records should be made available for convenient inspection.
- 5.1.2 The distribution record maintained with respect to a device product shall be retained for the longer of one of the following:-
- The projected useful life of the device product as determined by the manufacturer;
 - Two years after the date the device product is shipped.

For device products that are imported for export only, it is two years after the date the device product is shipped out of Tanzania.

5.2 Legal Records

- 5.2.1 Sales records should be maintained for any sale of device products by wholesale. A record of receipts and sales of the device products shall be kept, stating the device product name, pack size, date of transaction, invoice/delivery order number, name and address of purchaser/supplier, batch number, expiry date, quantity received/sold and stock balance.
- 5.2.2 All records must be readily retrievable, store and retained.

5.3 Electronic Records

- 5.3.1 Data especially legal records may be recorded by electronic data processing systems but detailed procedures relating to the system should be available and the accuracy of the records should be checked.
- 5.3.2 A written detailed description of the system should be produced (including diagrams as appropriate) and kept up to date. It should describe the principles, objectives, security measures and scope of the system and the main features of the way in which the computer is used and how it interacts with other systems and procedures.
- 5.3.3 Only authorized personnel should be allowed to enter or modify data in the computer. Access should be restricted by passwords or other means. User should have a unique identifier (User ID) for their personal and sole use so that activities can subsequently be traced to a specific individual.
- 5.3.4 There should be a record of changes and deletions. Any alteration to an entry of critical data should be authorized and recorded with the reason for the change. Consideration should be given to the system creating a complete record of all entries and amendments (an “audit trail”)
- 5.3.5 Records stored electronically should be protected by back-up transfer on magnetic tape, microfilm, paper or other means, at regular intervals. It is particularly important that the data including audit trail, are readily available throughout the period of retention. Back-up data should be stored as long as necessary at a separate and secure location.

6. HANDLING OF DEVICE(S) COMPLAINTS

- 6.1 Written procedure describing the actions to be taken in the handling of all written and oral complaints regarding a device product should be available. There should be a record for each individual complaint.

- 6.2 The procedure for handling complaints shall ensure that the complaints received are investigated and followed through that corrective actions are taken to prevent repeated complaints and where a decision is made to recall the device product, the details of the recall.
- 6.3 Within the company, a person shall be designated to handle complaints. This person must have the authority to initiate investigations. All investigations should be documented in writing.
- 6.4 If a device product defect is discovered or suspected in a batch, consideration should be given to determine whether other batches are also affected.
- 6.5 The investigation should take into consideration the condition and circumstances under which the device product was distributed, stored and used.

Note:

Complaints regarding a device product or its packaging distinct from those relating solely to matters within the distribution chain's control, must be notified promptly to the manufacturer. When the complaint is an adverse event related to a device product, TFDA must be notified promptly.

- 6.6 An investigation report must be put up with all corrective/preventative actions clearly stated.
- 6.7 Complaints records should be reviewed regularly for any indication of specific or recurring problems requiring attention.

7. RECALL OF DEVICE(S)

- 7.1 An emergency plan for urgent recalls and non-urgent device product recalls procedure should be described in writing.
- 7.2 A person should be designated for the co-ordination and execution of all device product recalls
- 7.3 In the event of a recall, all customers to whom the device product has been distributed shall be informed with the appropriate degree of urgency.
- 7.4 The recall message should indicate whether the recall needs to be carried out at the retail level and whether there is a need to remove all recalled device products immediately from the shelves and prevent their mixing with other saleable stocks.

- 7.5 The Authority should be informed for all recalls. If the device product is exported, the overseas counterparts and/or regulatory authorities must be informed of the recall.
- 7.6 Where recall affects a particular batch, consideration should also be given to determine whether other batches/materials are also affected.
- 7.7 All actions taken in connection with the recall must be approved by the company and/or TFDA and recorded.
- 7.8 Upon completion of the recalls, a final report must be provided to TFDA.
- 7.9 Reconciliation should be made between delivered and recovered quantities of device products.

8. HANDLING OF RETURNED DEVICE(S)

- 8.1 Written procedures describing the handling of returned device products and the corresponding records of all returns should be kept.
- 8.2 All returned device products should be kept apart from saleable stock to prevent redistribution until a decision has been reached regarding their disposal.
- 8.3 Device products should only be returned to saleable stock if:-
- The device products are in their original unopened containers and in good condition;
 - It is known that the device products have been stored and handled under proper conditions;
 - The remaining shelf life period is acceptable and
 - The device products have been examined and assessed by appropriate personnel. This assessment should take into account the nature of the device product, any special storage conditions required and the time that has elapsed since it was distributed. Special attention should be given to thermo-labile device products. Advice should be sought from the manufacturer as necessary.
- 8.4 The returned device products should be formally released to saleable stock by a nominated, responsible person following a satisfactory quality re-evaluation
- 8.5 Device products returned to saleable stock should be placed in accordance with the EEFO/FIFO system

9. COUNTERFEIT, ADULTERATED, UNWHOLESOME AND TAMPERED DEVICE PRODUCTS

- 9.1 Any counterfeit, adulterated, unwholesome and tampered device product found in the distribution network should be physically segregated from other device products to avoid any confusion. They should be clearly labeled as “Not for Sale” or other similar phrases/words.
- 9.2 The regulatory authority, registrant and manufacturer should be informed immediately.

10. CONTRACT ACTIVITIES

- 10.1 Any activities performed, referenced in the GDP guideline and delegated to another party, should be agreed upon in a contract.
- 10.2 There should be a written and approved contract or formal agreements between the contract giver and contract acceptor that addresses and defines in detail the responsibilities and GDP requirements for each party.
- 10.3 The contract should permit the Contract Giver to visit the facilities of the Contract Acceptor.

Note:

Any contract acceptor should be audited periodically as part of the GDP compliance.

- 10.4 Depending on the nature of activities performed, the Contract Acceptor should understand that he or she might be subject to inspection by the regulatory authority.
- 10.4 Repacking or re-labelling of device products must not be performed throughout the distribution supply chain, unless it is instructed by the manufacturer or is part of a corrective action.

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