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THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

GUIDELINES FOR PREMISES LICENSING AND GOOD DISTRIBUTION AND STORAGE PRACTICES

(*Made under Section 52(1) of the Tanzania Medicines and Medical Devices Act, 2003*)

First Edition
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Acknowledgements

This is the second revision of the guidelines for premises licensing and Good Distribution and Storage Practices (GDSP) to be developed by the Tanzania Medicines and Medical Devices Authority (TMDA). The revision has been made to embrace the new changes, knowledge, and experience gained during implementation of the previous edition.

We would like to thank TMDA staff who contributed to the successful review and development of these guidelines. Acknowledgements are particularly extended to Mr. Bryceson Kibassa, Ms. Rehema Mariki, Mr. Felix Zelote, Dr. Shani Maboko, Mr. Edinanth Gareba, Ms. Rose Maingu, Mr. Prosper Mwandepa, Ms. Marina Sapali, Mr. John Magambo and Ms Irene Rubona.

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Abbreviations

FEFO	-	First-Expired-First-Out
FIFO	-	First-In-First-Out
GDSP	-	Good Distribution and Storage Practices
IVDs	-	In-Vitro Diagnostics
MAH	-	Market Authorization Holder
QA	-	Quality Assurance
QMS	-	Quality Management System
SOP	-	Standard Operating Procedure
TMDA	-	Tanzania Medicines and Medical Devices Authority

Foreword

Tanzania Medicines and Medical Devices Authority (TMDA) was established under the Tanzania Medicines and Medical Devices Act, Cap 219 to regulate among other things the importation, exportation, manufacture, storage and distribution of medicines and medical devices.

These guidelines have been reviewed following the experience obtained through the implementation of the Guidelines for Good Distribution Practices of Medical Devices, First Edition of January 2011. It merges details on how to uphold good distribution and storage practices with the requirements for premises registration. Thus, the intention of this document is to provide comprehensive guidance to dealers of medical devices, diagnostics and laboratory equipment and the public on the procedure for submitting applications, requirements for registration of premises and licensing of the businesses as well as Good Distribution and Storage Practices (GDSP) of the products.

The development of these guidelines has taken into consideration TMDA's core values, in particular transparency; hence details on how the Authority handles each application have been documented to make our esteemed stakeholders aware of our internal processes and timelines.

The Guidelines for Premises Registration and Good Distribution and Storage Practices of Medical Devices, Diagnostics and Laboratory equipment is intended to complement the relevant regulations under the Tanzania Medicines and Medical Devices Act, Cap 219.

Dealers of the mentioned products are encouraged to familiarize themselves with these guidelines as it provides guidance on the best practices which if implemented will ensure that the quality, safety and performance of the products is maintained throughout the supply chain.

Being conversant of the diversity in medical devices, these guidelines have attempted to provide detailed and specific requirements for different types of dealers. Nevertheless, all dealers are encouraged to consult the Authority in any incidence where more clarification on the requirements is needed. We also welcome all users and the general public to give comments and views at any time as these guidelines may be revised regularly in response to experience gathered from their utilization.

Adam M. Fimbo
Director General

Definition of terms

In the context of these guidelines, the following terms shall be defined as follows:

Act
Means Tanzania Medicines and Medical Devices Act, Cap 219.

Authority
Means Tanzania Medicines and Medical Devices Authority.

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

Diagnostic devices
Means devices used to identify the nature or cause of a certain phenomenon, usually related to a medical condition.

Distribution
Means supply or movement of products from 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 by TMDA or entitled to distribute medical devices, diagnostics and laboratory equipment.

Expiry date
Means the date up to which the product is expected to remain within specifications, if stored correctly.

First-Expired-First-Out
Means a distribution practice that ensures that the stock with the earliest expiry date is distributed and/or used before an identical stock item with a later expiry date is distributed.

First-In-First-Out
Means a distribution practice 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
Means part of quality assurance that ensures the quality of the medical devices, diagnostics and laboratory reagents are maintained through adequate control throughout the numerous activities which occur during the distribution process.

Health Sciences
Health science is the discipline of applied science which deals with human and animal health.

There is a number of specialities under health sciences including pharmacy, pharmaceutical technology, biomedical engineering, medical laboratory technology, nursing, medicine, dentistry and veterinary science.

In Vitro Diagnostic Device (IVD)
A device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles.

Importer
Means a person or institution licensed and/or authorized to import medical devices, diagnostics, and laboratory equipment into the country.

Labeling / information supplied by the manufacturer
Written, printed or graphic matter affixed to the products or any of its containers or wrappers, or, accompanying the products, related to identification, technical description, and use of the products, but excluding shipping documents.

Laboratory Equipment
Means tools, apparatus and equipment used by scientists to perform research, scientific experiments, diagnosis for health care delivery on human and/or animals.

Market Authorization Holder (MAH)
An applicant who legally holds rights to place a particular product in the market.

Medical devices
Means any instrument, apparatus, laboratory equipment and reagent, implement, machine, appliance, implant, in vitro reagent, or calibrator, software, material or other similar or related article which is intended by manufacturer to be used alone or in combination for human beings or other animals, for the following purpose of: -
(a) diagnosis, prevention, monitoring treatment or alleviation of diseases or compensation for an injury;
(b) investigation, replacement, modification, support, the anatomy or of a physiological process;
(c) supporting or sustaining life;
(d) control of conception; or
(e) providing information for medical or diagnostic purposes by means of vitro examination or specimen derived from the human body or other animal, except that it does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means

Materials
Substances of a defined quality used in the production of medical devices and in vitro diagnostics but excluding packaging materials.

Product
Means a medical device, in-vitro diagnostic device and laboratory equipment.

Premises
Means land, building, structure, basement and vessel and in relation to any building includes a part of a building and any cartilage, forecourt, yard, or place of storage used in

connection with building or part of that building; and in relation to “vessel”, means ship, boat, air craft, and includes a carriage or receptacle of any kind, whether open or closed

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

Quality Assurance (QA)
Is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is a totality of the arrangements made with the object of ensuring that products are of the quality required for their intended use.

Quality Management System (QMS)
Is the aspect of management function that determines and implements the quality policy that is; the overall intention and direction of an organization regarding quality as formerly expressed and authorized by top management.

Qualified personnel
A person who is technically qualified through education, training and experience to perform designated tasks necessary to ensure proper operation within the premise.

Quality system
An appropriate infrastructure, encompassing the organizational structure, procedures, processes and resources, and systematic actions necessary to ensure adequate confidence that a product will satisfy given requirements for quality.

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

Standard Operating Procedure (SOP)
An approved and documented procedure giving instructions for performing given operations.

Superintendent
Qualified personnel who is in charge of the premise and is responsible for overseeing all operations and activities conducted.

1.0 Introduction

Registration of premises is the process of approving and licensing dealers to conduct business in medical devices through issuance of business permits and premise registration certificates. It is prompted by the need to ensure that all areas that conduct business in medical devices are suitable for operating without compromising the integrity of their products. This coincides with ensuring quality assurance of products and compliance to Good Distribution and Storage Practice (GDSP).

GDSP is the part of quality assurance that ensures quality of products is maintained throughout the supply chain. It lays down principles and defines measures to be taken by distributors during distribution process.

These guidelines provide detailed requirements for registering premises before starting business as well as best practices for conforming to GDSP. The guidelines provide further information regarding:

a) G
eneral information on the premise registration process from the initial application process and including steps undertaken by the Authority preceding issuance of permits;

b) Principles of GDSP including an overview of the mandated quality management systems requirements including but not limited to personnel, premise requirements, stock handling, transportation and delivery of products, installation and servicing, contract activities as well as maintenance of documents;

c) General conditions of premises outlining the requirements and maintenance of the external and internal surrounding of premises;

d) Specific requirements for retailers, wholesalers, importers, and warehouses; and

e) Requirements for secondary assembly/repacking.

It further outlines the requirements for handling of complaints, recall, returned as well as substandard and falsified product(s).

While manufacturers are also covered by these guidelines in terms of premise registration and business permits, they require a further step; quality audit before they can start their operations. The requirements for quality audit are not covered in these guidelines. Thus, all manufacturers must consult the Quality Audit Guidelines and ensure that they fulfil those requirements as well.

2.0 General information

This section provides valuable information about types of Premises, premises licensed by the Authority and all necessary information about premises licensing procedures that will enable applicant(s) to comply with the requirements for Premises licensing.

2.1 Types of premises

The premises under these guidelines shall be classified in the following categories: -

a) manufacturing facilities;
b) importing wholesalers;
c) wholesalers
d) warehouses;
e) retailers;
f) institutional pharmacies;
g) veterinary practice facilities;
h) vehicles;
i) medical laboratory facilities; and
j) any other premises as the Authority may designate.

All owners of premises shall ensure that, storage, transportation and distribution of regulated products is done in registered premises in accordance with the Act, Veterinary Act, Private Health Laboratories (Regulation) Act or any other applicable law.

2.1.1 Categories of domestic manufacturers

Domestic manufacturers of medical devices, diagnostics and laboratory equipment are categorized based on their production scale into small-scale manufacturers, medium-scale manufacturers and large-scale manufacturers. The criteria used to categorize these manufacturers is based on:

a) Capital invested in the industry or facility;
b) Source of raw materials used during production;
c) The technology in terms of machinery and equipment used during production;
d) Number and expertise of staff; and
e) The main market/target customer of the finished product.

The parameters used to fit each manufacturer in the different criteria are outlined in **Annex II**. All domestic manufacturers are required to refer to these criteria prior to lodging their applications so as to ensure the proper fees and charges are applied.

2.2 Premises licensing

Section 18 of the Tanzania Medicines and Medical Devices Act, Cap 219 restricts manufacturing for sale, sell, supply or storage of medical devices, in-vitro diagnostic devices and laboratory equipment unless the premises have been registered by the Authority.
The following are categories of premises dealing with medical devices and diagnostics that need to be licensed by the Authority prior to operation:

a. manufacturing facilities;
b. importing wholesalers;
c. wholesalers;
d. warehouses; and
e. Retailers.

2.2.1 Applications

All applications for premises registration and business licensing to operate as an importer, wholesaler and retail business shall be made online through TMDA Customer Self-Service Portal https://imis2.tmda.go.tz.

2.2.2 Types of applications

a) New premises applications.
b) Renewal applications.
c) Variation applications.

2.2.3 Documentation requirements

The following documents shall apply for each of the mentioned category of premises during applications.

2.2.3.1 Retailers, wholesalers and importing wholesalers

a) A copy of lease agreement or other agreement in terms of which the applicant has the right to occupy the proposed premises

b) If he is the owner of the premises, should submit certified copy of the title deed or similar document evidencing his right of occupancy of such premises;

c) A copy of the site plan of the building indicating the location of the premises in relation to adjoining or surrounding businesses and access to and from such premises;

d) A copy of the plan layout of the actual premises

e) Copy of Taxpayer Identification Number (TIN) issued by Tanzania Revenue Authority (TRA).

f) Copy of certificate of superintendent from any medical field (certificate level/diploma/advance diploma etc).

g) Commitment letter from superintendent or signed contract (if applicable).

h) A copy of certificate of Registration from the Business Registration and Licensing Agency (BRELA),

i) A copy of Memorandum and Articles of Association (if applicable)

2.2.3.2 Manufacturing facilities

a) A copy of certificate of Registration from the Business Registration and Licensing Agency (BRELA)

b) A copy of Certificate of Incentives from the Tanzania Investment Centre (TIC) if applicable.

c) A copy of Memorandum and Articles of Association

d) An approval from the National Environment Management Council (NEMC) on suitability of a site/plot for medical devices manufacturing activities.

e) Schematic drawing of a proposed manufacturing plant depicting premises layout, air handling system and specific location of equipment. Premises layout should among other things indicate ancillary, storage, weighing, and production and quality control areas.

2.2.4 Payment of Fees

a) Every application shall be accompanied by premises registration fees as specified in the Fees and Charges Regulations currently in force at the time of application.

b) All payments shall be made using control number indicated on the Invoice generated
against the application.

2.2.5 Processing of Applications

a) The Authority shall conduct screening of submitted applications to confirm completeness of submission before issuing invoice for payment of premises registration.

b) Incomplete applications will be queried for additional data and return back to the applicant for rectifications.

c) When the application has been accepted and appropriate fees paid physical inspection will be scheduled.

d) Then inspection of the premises should be conducted as per Inspection Checklist. Thereafter the premises registration certificate and business permit shall be issued by the Authority specifying the scope of licensed activity.

e) Manufacturing facilities after being issued premises registration certificate and business permit, are required to apply for quality audit as stipulated in the Quality Audit manual for medical devices and diagnostics manufacturing facilities.

A step wise description of the application processing is provided in figure 1 below

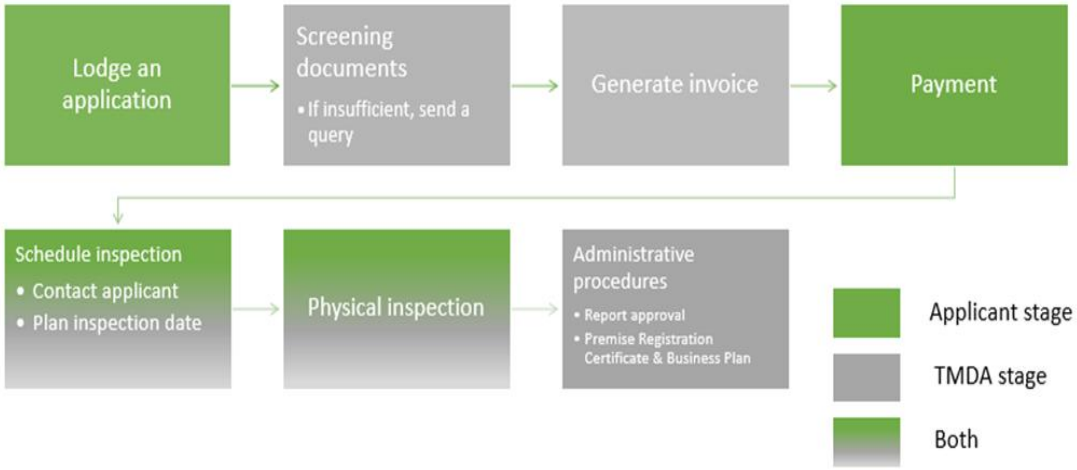

Figure 1: A summary of the premise licensing application process

2.2.6 Validity of premises registration certificate and business permit

a) Premises registration certificates shall be issued once and shall remain valid provided that:

(i) the business starts to operate within six (6) months from the date of approval or registration;

(ii) business permit is renewed annually;

(iii) the premises have been maintained and remains in conditions which led to its initial registration;

(iv) no change of ownership in case of natural person, business name or location without notice to the Authority; and

(v) The business permit shall be annually renewed unless suspended, cancelled or revoked by the Authority.

b) Business permits issued by the Authority shall expire on the 30th day of June every year. Thereafter, the applicant shall be required to apply for renewal of the business permit.

2.3 Application for Renewal of the Business Permit:

During the renewal of business permit, the applicant should submit the documents that were submitted during registration of the premises. However, re-inspection may be conducted as the Authority may deem necessary following the previous inspection reports.

2.4 Refusal or revocation of registered premises

The Authority may by giving reasons refuse to register any premises, and may at any time suspend, cancel, revoke or amend premises registration certificate, permit or both.

2.5 Review and appeals

Any person aggrieved by a decision of the Authority in relation to any application for registration of premises or permit may apply for review of the decision to the Director General.

The Authority may review its own decision, reject or vary the condition for approval. After reconsideration of the application, if the applicant is dissatisfied by the decision for review, may appeal to the Minister responsible for Health.

2.6 Notification for change of registered premises

a) Any change of location (shift of premises), trade name of the premises, ownership or any other change of registered premises, shall submit the application for change in the TMDA Online Portal.

b) When applying for change of registered premises, the applicant should upload notification letter and relevant documents for the new changes including the previous documents before changes.

c) The Authority shall have final say on the location and name of the proposed premises.

2.7 Cessation of business

2.7.1 The Authority may at any time suspend a permit as it may determine, or revoke, or vary any provisions of such permit. Such suspension and/ or revocation shall lead the Authority to revoke the premises registration certificate.

2.7.2 Any permit that has been suspended and/ or revoked in accordance with the provision of the Tanzania Medicines and Medical Device Act, Cap 219 may not be renewed except with the consent of the Authority if satisfied with the reasons given by the permit holder.

2.7.3 The Authority among other reasons may issue or declare a business closed down and deleted from the register, if for any reason such premises will be

found operating contrary to the prescribed requirements and standards stipulated in the Act.

2.7.4 If the proprietor wishes to close down his business because of any reason(s), he shall officially inform the Authority in advance.

2.7.5 A business that has been issued with a closure order shall surrender the premises registration certificate and valid business permit.

3.0 General principles of Good Distribution and Storage Practices (GDSP)

3.1 Quality management

3.1.1 All importers and distributors should have documented quality policies describing the overall intentions and policies regarding quality of the products they are distributing.

3.1.2 All dealers of medical devices, diagnostics and laboratory equipment shall institute and implement quality management system which includes: -

a) an appropriate infrastructure or “quality system” encompassing the organizational structure, procedures, processes and the resources;

b) Systematic actions necessary to ensure adequate confidence that a product and /or service and documentation will satisfy given requirements for quality. The totality of these actions is termed “Quality assurance”.

c) competent personnel;

d) Suitable and sufficient premises, equipment and facilities.

3.1.3 A designated person shall be appointed at each distribution point who shall have defined authority and responsibility for ensuring that a quality management system is implemented and maintained.

3.1.4 Authorized procurement and release procedures shall be in place to ensure that raw materials and products are sourced from approved suppliers and distributed to approved entities.

3.1.5 The owner of premises shall have a system to assess, control, communicate and review risks identified at all stages in the supply chain. The evaluation of the risk shall be based on scientific knowledge and experience, and ultimately be linked to the protection of the patient or consumer.

3.1.6 The owner of premises shall establish a system for periodic management review which shall include the following: -

a) review of the quality system and its effectiveness by using quality metrics and key performance indicators;

b) identification of opportunities for continual improvement; and

c) Follow up on recommendations from previous management review meetings.

3.1.7 There shall be written procedures and records to ensure traceability of the products distributed.

3.1.8 Authorized Standard Operating Procedures (SOPs) for all administrative and technical operations performed shall be in place.

3.1.9 In any case where some duties are delegated or contracted out the activities shall be documented in contracts and shall be periodically audited with regards to application of GDSP.

3.2 Personnel

3.2.1 All device premises should be supervised by a superintendent. The superintendent should have sufficient education qualifications in health sciences or any other specialty as the Authority deems necessary. The minimum qualification requirements are:

a) Retail dealers – diploma level; and
b) Importer and wholesaler – bachelor degree.

3.2.2 The correct distribution of medical devices, diagnostics and laboratory equipment relies upon qualified personnel. For this reason, there must be sufficient competent personnel to carry out all the tasks for which the dealers of these products are responsible. Individual responsibilities should be clearly understood by the staff and be recorded.

3.2.3 The personnel in charge of distribution of medical device including laboratory equipment should be registered by the respective professional boards/ councils.

3.2.4 There shall be an adequate number of competent qualified personnel involved in all stages of the distribution of the products in order to ensure that the quality of the products is maintained. Depending on categories of premises dealing with medical devices and diagnostics requirements is as indicated below;

a) Retail dealers – Minimum of certificate level in health sciences and any other specialties as the Authority deems necessary.

b) Importers/and wholesaler – Minimum of diploma level in health sciences and any other specialties as the Authority deems necessary.

3.2.5 Personnel involved in manufacturing and distribution of medical devices, diagnostics and laboratory equipment shall have the education, training,

experience or combination of these elements that will allow them to effectively discharge their responsibilities.

3.2.6 The superintendent shall be independent from the personnel responsible for operations and shall ensure compliance with good storage and distribution practices.

3.2.7 The owner of premises shall recruit other personnel and provide adequate resources needed to carry out their duties and follow the quality systems, as well as to identify and correct deviations from the established procedures.

3.2.8 Personnel dealing with sensitive and /or hazardous medical devices and diagnostics such as active, biological, radiation emitting or energy source components and products presenting risks of fire or explosion should be given specific training.

3.2.9 Personnel involved in the distribution of medical devices and diagnostics shall wear working or protective gears suitable for the activities that they perform. Personnel dealing with hazardous products and materials (such as active, toxic and infectious or sensitizing products) shall be provided with protective gears as necessary.

3.2.10 Personnel involved in the distribution of products shall abide to good hygiene practice to rule out contamination of products.

3.2.11 The superintendent shall ensure that personnel receive initial and continued training in accordance with a written training programme. The training may cover the requirements of good storage and distribution practices.

3.2.12 The owner of premises shall make arrangements to ensure that management and personnel are not subjected to commercial, political, financial or other pressures or conflict of interest that may have an adverse effect on the quality of service provided or on the integrity of products.

3.2.13 The owner of premises shall ensure that, procedures and conditions of employment, including contract and temporary staff, and other personnel having access to products, are designed and implemented to assist in minimizing the possibility of such products coming into the possession of unauthorized persons or entities.

3.2.14 The owner of premises shall ensure that, codes of practice and procedures are in place to prevent and address situations where persons involved in the storage and distribution of products are suspected of, or found to be implicated in, any activities relating to the misappropriation, tampering, diversion or falsification of any product.

3.2.15 Location

a) The premises shall be located away from sites or activities that emit noxious materials like fumes, contaminants, open sewerage etc or any other place where safety, quality and performance of the products can be compromised.

b) The premises should be located such that they meet the requirements prescribed by the National Environment Management Council (NEMC) and Occupational Safety and Health Authority (OSHA).

c) The premises shall be designed such that, it shall have no direct link to building with bar, restaurant and residential houses where the business is housed.

d) The premises should have postal and physical addresses including plot and house numbers, street/hamlet, district and region where the business is to be carried out, clearly indicated in the online application form for easy location and identification.

3.2.16 Building

a) Building must be of permanent construction and address.

b) The finishing of walls, ceiling and floors shall be such that, they are easy to clean. The building shall be kept clean and maintained.

c) Sufficient lighting and ventilation shall be provided to enable all operations to be carried out.

d) Buildings should protect products from contamination and deterioration, including protection from excessive heat or undue exposure to direct sunlight.

e) Buildings should have sufficient security to prevent unauthorized access and misappropriation of the products.

f) Building should be constructed, serviced and maintained regularly to protect stored products, from all potentially harmful influences such as undue variations of temperature and humidity.

g) Receiving and dispatch bays shall protect products from the extreme climate conditions. Reception areas shall be designed and equipped to allow containers of incoming products to be cleaned.

h) The surrounding should be maintained to minimize dust, soil, pests and other contamination to enter the building.

3.2.17 Layout

a) Medical devices, diagnostics and laboratory equipment retail premises shall have a sufficient storage area to allow orderly storage of products.

b) Importers and wholesale outlets shall have a sufficient storage area to allow orderly storage of medical devices and not less than two rooms with clear demarcation and linked to each other for display / dispatch and storage.

c) The rooms should be equipped as indicated in the inspection checklist (Annex II) with adequate shelves and/or pallets for proper display and storage of the products.

d) Warehouses shall be designed and constructed to ensure good storage conditions, sufficient lighting and ventilation.

e) A residential house with human habitation shall not be used as a warehouse.

3.2.18 Sanitation

a) Premises should be kept clean at all time and waste should be removed at regular intervals.
b) The premises shall have a toilet facilities or nearby accessible toilet.

3.2.19 Storage area

a) Precautions must be taken to prevent unauthorized persons from entering storage area.

b) Where controlled environmental storage conditions are required, these conditions should be continuously monitored and documented. Appropriate actions, on the premises, 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 20˚C and 30˚C

Whereas storage conditions stated on the label mean the following:

On the label	**Guidance value**
Protect from moisture	No more than 75±5% 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

a) Storage area shall be clean, dry and free from accumulated wastes, spillage, vermin and pests. There shall be a written sanitation and pest control program indicating the frequency of cleaning and methods to be used to clean the premises and storage area. The pest – control agent used shall be safe with no risk of contamination of the products.

b) Products shall be stored off the floor and suitably spaced to permit cleaning and inspection. Pallets shall be kept in a good state of cleanliness and repair.

c) Storage area shall be provided with adequate light to enable all operations to be carried out accurately and safely

d) Storage areas shall be of sufficient capacity with clear demarcation to allow orderly arrangement of the various categories of products namely quarantined, rejected, returned or recalled products, expired, substandard and falsified products.

e) Sensitive and/or hazardous products such as highly active and radioactive materials, products presenting risks of fire or explosion (e.g. combustible liquids, solids and pressurized gases) shall be stored in a dedicated area that is subject to appropriate additional safety and security measures.

3.4 Storage of products

3.4.1 Products shall be stored separately from other products regulated by the Authority (i.e Medicines) and shall be arranged in a logical manner. Attention should be paid to manufacturer's instructions.

3.4.2 Products due to expire first shall be sold and /or distributed first (FEFO principle) and where product have the same expiry dates the FIFO principle shall be applied.

3.4.3 Products that have been damaged or withheld from sale and which are not immediately destroyed shall be placed under quarantine until disposal so that they cannot be sold in error or /in the case of liquid leakage, cause contamination of other goods.

3.4.4 Theft and losses of products shall immediately be reported to police and the Authority within 48 hours.

3.4.5 If sampling is performed in the storage area, it shall be conducted in such a way as to prevent contamination or cross-contamination and adequate cleaning procedures shall be in place for the sampling areas.

3.5 Stock handling and control

3.5.1 Handling and storage of products shall be in such a manner as to prevent contamination, deterioration and damage, mix-up and cross-contamination.

Attention shall be paid to manufacturer's instructions.

3.5.2 Periodic stock reconciliation shall be performed by comparing the actual and recorded stocks and all significant stock discrepancies shall be investigated as a check against inadvertent mix-ups and /or incorrect issue.

3.6 Receiving of Products

3.6.1 All materials and products received shall be verified and certified against order and delivery note, in particular the physical quantities, batch number/serial number unit of issue, package size, expire date and damaged goods.

3.6.2 Products subject to specific storage measures (e.g. controlled products requiring specific storage condition) shall be immediately identified and stored in accordance with manufacturer's instructions and relevant guidelines.

3.6.3 Products rejected because of expiry, error, breakage, leaking containers or other faults shall be identified and controlled under quarantine until a final decision is taken on their fate.

3.6.4 A person receiving a consignment of products shall ensure that: -

a) each incoming delivery is checked against the relevant documentation, to ensure that the correct product is delivered from the correct supplier which may include, the purchase order, containers, label description, batch or lot number, expiry date, product, quantity, certificate of analysis or certificate of conformity, where applicable;

b) the consignment is examined for uniformity of the containers and, if necessary, is subdivided according to the supplier's batch or lot number; in case the delivery comprises more than one batch: Provided that, where the consignment has more than one batch, each batch shall be dealt separately;

c) a representative number of containers in a consignment is sampled and checked according to a written procedure and any suspect containers or, if necessary, the entire delivery, quarantined for further investigation;

d) receiving areas are of sufficient size to allow for the cleaning of incoming products;

e) when required, samples of products are taken by appropriately trained and qualified personnel and in strict accordance with a written sampling procedure

and sampling plans: Provided that, where sampling has been done containers from which samples have been taken shall be labelled accordingly;

f) following sampling, the products are subject to quarantine and batch segregation maintained during quarantine and all subsequent storage, where applicable;

g) Products that require controlled conditions for storage and transportation should be handled as priority. Ensure that the required conditions of transport and storage are maintained throughout the handling of the products.

h) Products are not transferred to saleable stock until an authorized release is obtained.

i) Measures are taken to ensure that rejected products cannot be used, are segregated and securely stored while awaiting destruction or return to the supplier.

3.7 Handling of returned products

3.7.1 All returned products shall be kept apart from saleable stock to prevent re-distribution until a decision has been reached regarding their disposal.

3.7.2 Products should only be returned to saleable stock if:-

a) They are in their original un-opened containers and in good condition;

b) It is known that the products have been stored and handled under proper conditions;

c) The remaining shelf-life period is acceptable; and

d) The products have been examined and assessed by appropriate personnel. This assessment should consider the nature of the product, any special storage conditions required and the time that has elapsed since it was distributed. Special attention should be given to thermo-labile products. Advice should be sought from the manufacturer as necessary.

3.7.3 Returned products should be formally released to saleable stock by a nominated, responsible person following a satisfactory quality re-evaluation.

3.7.4 Products returned to saleable stock should be placed in accordance with the FEFO/FIFO system.

3.7.5 Re-conditioning, re-packaging, or re-labelling of the products shall not be carried out by any distributor unless they hold a license for such activity issued by the Authority or is specifically exempted from the requirements to hold a manufacturer's license.

3.8 Recall and withdrawals

3.8.1 Products known or suspected to be defective shall be recalled from the market. The Authority, manufacturer, registrant, or importer of the products can initiate the recall.

3.8.2 In case of recall of product initiated by the manufacturer, registrant or importer, the Authority shall be notified on the reason of recall.

3.8.3 Depending on the degree of health risk that the defective product may cause, there are three classes of recall; Class I, Class II and Class III.

3.8.4 Class I recall is for defect that probably can result into serious health risks or adverse event or death. Class II recall is for product that may result to temporary or medically reversible adverse health problem or mistreatment; and Class III recall is for defect that are unlikely to cause any adverse health reaction.

3.8.5 The maximum time for class I recall, class II recall and class III recall shall be 14, 21 and 30 days respectively from the time when the defect was identified.

3.8.6 A progress report on the recall shall be submitted to the Authority weekly following the initiation of recall.

3.8.7 The distribution records shall be readily available to the person(s) responsible for recalls and they shall contain sufficient information related to the product, e.g. quantity, name of product, name and address of the manufacturer, dates of manufacture and expiry, and batch/lot number.

3.8.8 The applicant and /or distributor shall inform all customers, public and competent authorities of all countries to which a given product may have been distributed of any intention to recall the product because it is, or is suspected to be unfit.

3.8.9 All actions taken in connection with the recall must be approved by the company and/or Authority and recorded.

3.8.10 Upon completion of the recalls, a final report should be provided to Authority.

3.8.11 Reconciliation should be made between delivered and recovered quantities of the products

3.9 Substandard and falsified products

3.9.1 Suspected substandard or falsified products found in the distribution chain shall be kept apart from other products and clearly labelled “Not for Sale”. The applicant and the Authority should be informed immediately.

3.9.2 Upon confirmation of the products to be substandard / falsified, recall procedures should be instituted and followed by destruction.

3.9.3 The applicant shall be responsible for the quality, safety and performance of the product while on the market including recall of substandard products.

3.9.4 The owner of premises shall ensure that, sub-standard and falsified products do not re-enter the market.

3.10 Disposal of products

Expired, damaged, substandard, falsified products shall be dealt in accordance with the current Tanzania Medicines and Medical Devices (Control of Medical Devices) Regulations, 2015.

3.11 Transportation and deliveries to customers

Products shall be transported in such a way that:

a) Their identification is not lost e.g. Label
b) They do not contaminate and are not contaminated by other products or materials.
c) Adequate precautions are taken against spillage, breakage, or theft.
d) They are secured and not subjected to unacceptable degree of heat, cold, light, moisture or other adverse influence, or attacked by microorganisms or pests.

Vehicles for transportation of temperature sensitive medical devices, diagnostics and laboratory equipment should be qualified for their intended use. Special care should be exercised when using dry ice during transportation. Products should not come into contact with dry ice as this may cause freezing of the device. Vehicles should not be used as storage for devices.

The use of temperature monitoring devices on transit and during delivery is recommended. Such records should be reviewed for any possibility of out-of-range results during transportation chain.

Deliveries should be made only to authorized wholesalers, distributers, person authorized to supply or use medical devices, diagnostics and laboratory equipment.

3.12 Installation and servicing

3.12.1 Where installation of medical devices and diagnostics is a specified requirement, the owner of premises shall establish and maintain adequate installation and inspection instructions, and where appropriate test procedures.

3.12.2 Instructions and procedures shall include directions for ensuring proper installation so that medical devices will perform as intended after installation. Installation, inspection and any required testing are to be performed in accordance with the instructions and procedures.

3.12.3 The records of inspection and any test results to demonstrate proper installation shall be maintained by the owner of premises.

3.12.4 Where servicing is a specified requirement, the owner of the premises shall establish and maintain instructions and procedures for performing and verifying that services meet the specified requirements. Records of servicing shall be maintained.

3.12.5 Appropriately trained personnel should conduct installation and servicing of the devices.

3.13 Contract activities

3.13.1 Any activities performed or referenced in these guidelines and delegated to another party, should be agreed upon in a contract.

3.13.2 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 GDSP requirements for each party.

3.13.3 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 GDSP compliance.

3.13.4 Depending on the nature of activities performed, the contract acceptor should understand that he or she might be subject to inspection by the Authority.

3.13.5 Repacking or re-labelling of the products must not be performed throughout the distribution supply chain, unless it is instructed by the manufacturer or is part of a corrective action.

3.14 Importation of products

All importations shall be in compliance with the Act and current Regulations and Guidelines for Importation and Exportation of Medical Devices including In-vitro diagnostics and Laboratory equipment in force.

3.15 Documentation

3.15.1 There shall be written procedures for receiving, storage, dispatch, transportation, recalled, returned, expired, complaints, substandard and falsified products, and adverse events monitoring and recording.

3.15.2 An importer, exporter, distributor or supplier shall have in particular the following records:

a) TMDA inspection reports file;

b) complaints handling book;

c) unfit products register;

d) recall register (where applicable);

e) final invoices with corresponding import permits (where applicable);

f) copies of delivery notes;

g) sales invoices with batch/lot numbers.

The records referred above shall be kept and maintained within the premises for a period of not less than two (2) years after dispatch or the projected useful life of the medical device or in vitro diagnostic.

All documents shall be completed, approved, signed (as required) and dated by an appropriate authorized person(s) and shall not be changed without the necessary authorization.

3.16 Handling of Medical Devices Complaints

There should be a system of receiving, evaluating and classifying complaints.

3.16.1 Complaints relating to the wholesaler’s own activity shall be evaluated and measures taken, where appropriate, to prevent their recurrence.

3.16.2 All complaints and other information concerning potentially defective and potentially substandard and falsified medical devices or in-vitro diagnostics shall be reported to the marketing authorization holder and the Authority.

3.16.3 Any complaints concerning a material defect shall be recorded and thoroughly investigated to identify the origin or the reason for complaint.

3.16.4 Any complaints from users regarding medical devices adverse event/ incident shall be documented in the medical devices adverse event /incident reporting form(s) and should be reported to the Authority.

3.16.5 Complaints records should be reviewed regularly for any indication of specific or recurring problems requiring attention.

3.16.6 An investigation report must be prepared with all corrective/preventive actions stated clearly.

4.0 Specific Requirements for the Premises

Requirements for the different types of premises

4.1 Wholesale business

The premises for wholesale business should have the following requirements: -

4.1.1 At least two rooms: -

a) Display/Dispatch/Sales Record keeping room

There should be source of water, ceiling Fan/AC, waiting chair(s) for customers, Reception Desk and Lockable shelves for keeping documents p

b) Storage room

It should have Air Conditioner, Temperature and humidity monitoring devices, Strong door towards storeroom, Strong grilled window, Open shelves/pallets, Confined area for recalled and expired medical devices and diagnostics.

4.1.2 Personnel (Minimum of diploma level in health sciences and any other specialties as the Authority deems necessary)

4.2 For Retail Business

It should have an adequate space to allow orderly storage of medical devices. The premises for retail business should have the following requirements: -

4.2.1 At least two rooms: -

a) Display/Dispatch/Sales Record keeping room

There should be source of water, Ceiling Fan/AC, waiting chair(s) for customers, Reception Desk and Lockable shelves for keeping documents

b) Storage room

It should have air conditioner, temperature and humidity monitoring devices, Strong door towards storeroom, strong grilled window, Open shelves/pallets, Confined area for recalled and expired medical devices and diagnostics.

4.2.2 Personnel (Minimum of diploma level in health sciences and any other specialties as the Authority deems necessary).

4.3 For Warehouse/Godown

There should be sufficient air conditioners, temperature and humidity monitoring devices, Strong and well secured doors, Strong and well secured windows, Open shelves and pallets, Confined area for recalled and expired medical devices.

5.0 General Condition of Premises

5.1 External surrounding

a) Should not be directly linked to the bar
b) Should be away from source of noxious fumes
c) Should be away from Damp
d) Should be away from open sewage drainage
e) There should be an access to wash room

5.2 Internal surrounding

a) It should have a strong ceiling board and roofed with materials making it free from leakages.
b) It should be well protected from entry of rodents, birds, vermin and pets
c) Should have sufficient Lighting
d) Should have a cooling system
e) The floor should be durable and smooth (easy to clean)
f) Should be painted with white washable paint

6.0 Requirements for secondary assembly/repacking

6.1 General requirements

The size of assembly area should reflect the volume of assembly. The adequacy of the working space should permit the orderly and logical positioning of equipment and materials so as to avoid confusion and to minimize the risk of mix-up between different medical devices or their components. Segregated areas should be provided for the storage of approved, quarantined, rejected, recalled and returned materials or products.

Assembly areas should be well-lit and effectively ventilated, with air handling system

(including temperature, humidity and filtration controls) where appropriate. Smoking, eating and drinking should not be permitted in the assembly area.

The superintendent should ensure that all necessary controls are put in place to ensure that the repacking/secondary assembling process does not have an adverse or potential adverse effect on the quality of the medical device.

The amount of control and level of detail should be appropriate to the degree of criticality (e.g. based on the output of risk management activities) of the process in achieving the requirements for quality and the degree of training of personnel involved in the secondary assembly line.

6.1 Assembly documents

Any secondary assembly work instructions should include:

a) name of the product;
b) description of the applicable medical devices for assembly and pack size;
c) complete list of all the packaging materials required for a standard batch size, including quantities, sizes and types, with the code or reference number relating to the specifications of each packaging material;
d) where appropriate, an example or reproduction of the relevant printed packaging materials, and specimens indicating where to apply batch number references, and expiry date of the medical device;
e) special precautions to be observed, e.g. a careful examination of the area and equipment in order to ascertain the line clearance before operations begin;
f) description of the packaging operation, including any significant subsidiary operations, and equipment to be used; and
g) details of any in-process controls with instructions for sampling and acceptance limits, if applicable.

Records that facilitate traceability and review of the secondary assembly of a batch of medical device, derived during the secondary assembly of that batch, should be contained in a batch record, and frequently collated in a single file. Such files may be referred to as a “Device History Record”, “Batch Assembly Record”, “Lot History Record” or “Lot Record”.

If it is not practical to include all the relevant documents in the batch record, then the record should list the titles of those documents and their location(s).

During secondary assembly, relevant information should be entered into the batch record. Such information should include:

a) quantity of raw materials, components and intermediate products, and their batch number, if appropriate,
b) date of start and completion of different stages of secondary assembly;
c) quantity of medical device assembled;
d) signed results of all inspections and tests;
e) designation of the product line used; and
f) deviation from the secondary assembly specifications, if applicable.

Data may be recorded by electronic data processing systems, photographic or other reliable means, but detailed procedures relating to the system in use should be available and the accuracy of the records should be checked.

If documentation is handled by electronic data processing methods, only authorized personnel should be able to enter or modify data in the computer and there should be a record of changes and deletion; access should be restricted by passwords or other means and the result of entry of critical data should be independently checked.

Batch records electronically stored should be protected by back-up transfer on magnetic tape, microfilm, paper or other means. It is particularly important that the records are readily available and to ensure their integrity throughout the period of retention.

Records of batch/lot numbers and identities of all individual medical devices that are re-packaged or assembled during the secondary assembly process should be recorded and maintained to allow for traceability. Distribution records should be maintained for each batch of medical device in order to facilitate the recall of the batch if necessary.

References

1. Tanzania Medicines and Medical Devices Act, Cap 219;
2. Tanzania Medicines and Medical Devices (Control of Medical Devices) Regulations, GN 315;
3. Guidelines for Registration of Medical Devices and Diagnostics Premises, First Edition, 2011;
4. Guidelines Health Sciences Authority (HSA) – Singapore;
5. Official Journal of the European Union; Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use

INSPECTION CHECKLIST FOR NEW MEDICAL DEVICES PREMISES

TMDA/DMD/MDL/C/001
Rev: #2

(Made under The Tanzania Medicines and Medical Devices (Control of Medical Devices) Regulations, 2015)

This checklist must be correctly filled in capital letters and sent to the Director General, TMDA
Any false information entered in here by inspector(s) may lead the Director General, TMDA to take disciplinary action against the inspector(s).
Only inspectors as recognized by the Tanzania Medicines and Medical Devices Act, 2003, shall fill in this checklist.

REQUIREMENTS:

1. Name and address of the premises:……
……

2. Full name of proprietor:

(i) Individual……

(ii) Company……..

3. Name and Status of Superintendent:

Name ……..……..……Profession……

4. Location

(i) Plot No…….. Block No…….. House No……., Street/Hamlet,……..…..
District…….…….. Region……..……

(ii) GPS Coordinates……

5. Size of building and number of rooms/compartments:

A. Wholesale business

At least two rooms (i.e Display/Dispatch/Sales Record keeping room and Store room)

(a) Display/Dispatch/Sales Record keeping room ……Present/Not Present

- Presence of source of water ……Present/ Not Present
- Ceiling Fan/AC……Present/Not Present
- Waiting chair(s) for customers……..Present/Not Present
- Reception Desk……Present/Not present
- Provision of main entrance ……Yes/No
- Lockable shelves for keeping documents……..….Present/Not Present
- Any Other (mention)…….....

(b) Storage room……Present/Not Present

- Air Condition……Present/Not Present
- Temperature and humidity monitoring devices.....Present/Not Present
- Strong door toward storeroom……...Present/Not Present
- Strong grilled window……..Present/Not Present

- Open shelves/pallets……..Present/Not Present
- Confined area for recalled and expired medical devices……Present/Not Present

B. For Retail Business

a) Adequate space to allow orderly storage of medical devices

- Display/Dispatch area……Present/Not Present
- Presence of source of water …… Present/ Not Present
- Ceiling Fan/AC…… Present/Not Present
- Waiting chair(s) for customers……Present/Not Present
- Lockable shelves for keeping documents……Present/Not Present
- Provision of main entrance ……Yes/No
- Any other (present facility (mention)…….....

b) Storage area……Present/Not Present

- Air Condition…… Present/Not Present
- Temperature and humidity monitoring devices.....Present/Not Present
- Strong grilled window…… Present/Not Present
- Open shelves/pallets…….. Present/Not Present
- Confined area for expired medical devices……. Present/Not Present
- Any other (mention)……

C. For Warehouse/Godown

- Air Condition sufficient for providing the required cooling condition for respective medical devices……..……Present/Not Present
- Temperature and humidity monitoring devices.....Present/Not Present
- Strong and well secured doors…..……Present/ Not Present
- Strong and well secured window……..…...Present/Not Present
- Open shelves and pallets…….……Present/Not Present
- Confined area for recalled and expired medical devices……...Present/Not Present
- Any Other (mention)…….....

6. General condition of premises

A. External surrounding

(i) Not directly linked to the bar……Yes/No
(ii) Away from source of obnoxious fumes…… Yes/No
(iii) Away from Damp……Yes/No
(iv) Away from open sewage drainage…….Yes/No
(v) Availability / access to wash room .....Yes /No
(vi) Any other observed deficiencies…… Yes/No

B. Internal surrounding

(i) Presence of strong ceiling board…..……Yes/No
(ii) Lighting……Sufficient/Poor
(iii) Cooling system…… Sufficient/Poor
(iv) Durable and smooth floor (easy to clean) ……Yes/No
(v) Painted with white washable paint.....Yes/No

(vi) Strong and smooth walls (easy to clean) ……Yes/No

7. Any other Observation(s)……
……

8. Inspectors recommendation……
……
……

Inspectors declaration

We (names)	(Signatures)	(Date)
(i) ……..	……..	……
(ii) ……	……..	……
(iii) ……		……..
…….		
(iv) ……		……
…….		

Have inspected the above –mentioned premises and, we hereby admit that the information given above is TRUE and CORRECT. We understand that any given false information may lead the Director General, TMDA to take disciplinary action against us.

9. Owner's Certification

I (Full Name of Owner) ……
Certify that my premises has been inspected by the above-named inspectors and I agree with the observation provided.

…… ……
Owner's Signature Date

Annex II:

Categories of Domestic Manufacturers

CRITERIA	SMALL	MEDIUM	LARGE
CAPITAL	Less than TZS 50 M	More than TZS 50 M and less than 100 M	More than TZS 100M
SOURCE RAW MATERIALS	Mainly sources raw materials locally from registered dealers	Mainly sources raw materials locally but may also import	Mainly imports raw materials for production (not locally sourced)
TECHNOLOGY	Simple power-driven equipment	Simple power-driven equipment	Complex and advanced machines
STAFF	Semi-skilled Less than 20 employees	Semi-skilled, skilled Between 20 and 30 employees	Skilled and specialized More than 50 employees
TARGET MARKET	Sells products locally	Mainly sells products locally	Exports finished products and sell locally