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TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

GUIDELINES FOR IMPORTATION AND EXPORTATION OF MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS AND LABORATORY EQUIPMENT

(Made under Section 73(1) of the Tanzania Medicines and Medical Devices *Act, 2003)*

SECOND EDITION

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TMDA will welcome comments for improvement of these guidelines during implementation.

Hmsallah

Akida M. Khea

Acting Director, Medical Products Control

Tanzania Medicines and Medical Devices Authority

FOREWORD

In view of complexity of the medical devices and the accompanied risk in various ways of utilization, the Tanzania Food, Drugs and Cosmetics (Control of Medical Devices) Regulations, 2015 has laid down the rules pertaining to importation and exportation of medical devices including in vitro diagnostics, laboratory equipment and their accompanying spare parts. The guidelines requires any person dealing with importation of these products to obtain valid permit issued by the Authority for that purpose. The regulations further sets the requirements for application of the permits, issuance of the permits, conditions for importation of devices for personal use, designating the ports of entry, conditions for importation of donated medical devices and other related aspects of this important regulatory intervention.

The goal of these guidelines is to help manufacturers, importers, distributors and exporters comprehend the requirements to obtain approval to import and export medical devices in Tanzania. The guidelines provide information and documentation required in an application submitted to TMDA by an importer or exporter of medical devices. The guidelines also outline appeal procedures in the event an applicant is aggrieved by decision of the Authority.

All dealers involved in importing and exporting medical devices are encouraged to familiarize with these guidelines and follow them strictly when preparing and submitting applications. Adherence to these guidelines will ensure that all relevant information and documentation are submitted and therefore avoid unnecessary delays in approval process and hence expedite provision of quality services to clients.

The Authority would like to emphasize that the requirements in these guidelines have been provided to ensure that only medical devices of acceptable quality, safety and performance are imported into or exported out of the country. It is therefore expected that all concerned parties will adhere to the specified requirements in these guidelines.

A.M. Fimbo
Acting Director General
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INTRODUCTION

These guidelines have been developed to provide guidance for importers and exporters of general medical devices and in vitro diagnostics including laboratory equipment pursuant to legal requirements prescribed under regulation 45 of the Tanzania Food, Drugs and Cosmetics (Control of Medical Devices) Regulations, 2015.

The document applies to any person, institution and organization that intends to export or import for the purpose of selling, research or donation of medical devices in Tanzania mainland. The main objective of these guidelines is to provide importers and exporters of medical devices with the necessary information to enable them comply with the law and regulations governing importation and exportation of medical devices into and outside the country respectively. Other objectives include control of unwanted medical devices as well as minimizing the accumulation of non- functional medical devices but also to alleviate problems associated with donation by promoting good medical devices donation practice.

The document has been organized into four main chapters. The first chapter provides for the requirements and procedures to be followed during importation of medical devices, the second chapter describes procedures for donation of medical devices, the third chapter outlines the requirements and procedures for the exportation of medical devices and the fourth chapter outlines the review and appeal procedures in the events applicants are aggrieved by TMDA decisions. Formats of import and export permits have been appended for easy referencing.

Approval for importation, exportation and donation of medical devices will be based on fulfilment of the requirements prescribed in the Act, regulations, these guidelines and Guidelines published by the Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDEC). Applicants are advised to read and understand the requirements before applying for importation or exportation of devices.

DEFINITION OF TERMS

For the purpose of these guidelines the following terms shall be defined as follows:

Authority

Means the Tanzania Medicines and Medical Devices Authority, or its acronym "TMDA" established under section 4 (1) of the Tanzania Medicines and Medical Devices Act, Cap 219.

Consignment

Means a quantity of goods that are sent to a person or place to be sold.

Donation

Means an act or instance of presenting medical devices to recipients in emergency or as a part of development aid in non-emergency situations.

Donor

Means a governmental or nongovernmental organization or individual who voluntarily donates medical devices as a donation;

Exporter

Means a person or institution licensed and/or authorized to export medical devices outside the country.

Export Permit

Means a permit issued to exporter by the Authority, authorizing him to export medical devices from the country.

In Vitro Diagnostic Medical Device

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 into the country.

Import permit

Means a permit issued to importer by the Authority, authorizing him to import medical devices into the country.

Label

Means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on or attached to a container of any medical devices including in-vitro diagnostics.

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.

Manufacturer

Means a person who sells medical devices under their own name, or under a trade- mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labeling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf;

Medical Device or Devices

Refer to an instrument, apparatus, implement, medical equipment, machine, contrivance, implant, in vitro reagent, **In Vitro Diagnostic (IVD's),** 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.

Laboratory Equipment

Are tools and equipment used by scientists to perform experiment and take measurement in laboratory.

Permit

Means certificate of approval to import and export medical devices

Recipient

Means a governmental, non-governmental or private health institution that voluntarily receives medical devices as a donation;

1. CHAPTER ONE

IMPORTATION OF MEDICAL DEVICES INCLUDING LABORATORY EQUIPMENT

1.1. Categories of importers of medical devices including in vitro diagnostics:

Importers of medical devices including laboratory equipment shall fall under the following categories:

a) Authorized government and non-governmental institutions;

b) Medical devices and in vitro diagnostics wholesalers;

c) Clinical trial investigators;

d) Recipients of donations;

e) Persons importing medical devices for medical purposes;

f) Exhibitors;

g) Researchers.

1.2. Requirements for importers

All medical devices including laboratory equipment for human use to be imported must have marketing authorization (registration or notification) by TMDA unless given special approval by the Authority.

Medical devices for veterinary use are exempted from registration and therefore they should only be notified to the Authority.

All importation of medical devices including laboratory equipment must be done by importers whose premises are dully registered or auhtorized by TMDA.

All importers must import medical devices including laboratory equipment through the authorized ports of entry (POE).

In case of donations please refer **chapter two** of these guidelines.

All imported medical devices including laboratory equipment should be labelled in the manner consistent with information with approved labelling information during marketing authorization application. Particularly, the following minimum information should be contained on the label:-

a) Name of the device

b) Name and address of the manufacturer

c) The identifier of the device, including the identifier of a device that is part of a system, test kit, medical device group, medical device

d) Family or medical device group family *(where applicable)*

e) Batch or lot number

f) If the contents are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the device, such as size, net weight, length, volume or number of units

g) The words "sterile" if the manufacturer intends to sale the device in a sterile condition

h) The words "for single use only" if the device is intended for that purpose

i) The manufacturing and expiry date of the device expressed in month and year (*where applicable)*

unless self-evident to the intended user, the medical conditions, purposes and uses for which the device is manufactured, sold or represented, including the performance specifications of the device if those specifications are necessary for proper use

j) The directions for use, unless directions are not required for the device to be used safely and effectively and any special storage conditions applicable to the device

k) Where a package that contains a device is too small to display all the information in accordance with (a-k) above, the directions for use shall

accompany the device but need not be set out on the outside of the package or be visible under normal conditions of sell.

Labeling information shall be in English and/or Kiswahili and shall be expressed in a legible, permanent and prominent manner that can easily be understood by the intended user.

1.3. Procedure for importation of medical devices including laboratory equipment

a) Authorized importers intending to import medical devices including laboratory equipment shall apply for importation permit to Director General through the TMDA online portal.

b) The application shall be accompanied by one original proforma invoice from the marketing authorization holder of the product(s) or authorized supplier(s).

c) The proforma invoice shall state for each medical device to be imported, the following:-

i. Proforma invoice number and date;
ii. Name and address of the supplier;
iii. Name and address of the importer;
iv. Name and address of the manufacturer;
v. Country of origin;
vi. Clear description of items including brand and common names as declared in information of medical devices including laboratory equipment submitted to TMDA;
vii. The quantity, pack size, unit value, total value in convertible currency;
viii. Batch or Lot number;
ix. Manufacturing and expiring date;
x. Mode of shipment (sea, air, road);
xi. Port of entry;
xii. Signature and stamp of the supplier and/or manufacturer;

1.4. Processing of applications

Upon receiving the application as specified above, TMDA will scrutinize to verify whether the requirements have been fulfilled.

If the application meets the prescribed requirements, the applicant will be required to pay import fees as stipulated in the Fees and Charges Regulations in force, and the Authority will issue an import permit as set out in the **Annex I** of these guidelines.

An application, which does not meet any of the importation requirements, will not be approved. An applicant will be notified by the Authority stating clearly the reason(s) for rejection.

All applications will be processed within twenty-four hours (24) during working days with exception of special requests, which will be processed within ten (10) working days.

All importers will be required to hold a valid importation permit issued by the Authority prior to shipping of the consignment.

1.5. Special importation requirements

The same application requirements and procedures as prescribed under Sections 1.3 and 1.4 respectively shall apply. However, in some special circumstances the following requirements will be applicable.

1.6. Importation of unregistered medical devices and in vitro diagnostics

TMDA requires that application for the supply of unregistered devices be substantiated with the clinical justification including the special clinical needs of the unregistered devices by the qualified practitioner in place of registered products.

Capital equipment that are installed as part of health facility fixed infrastructure such as X-ray machines, Anesthesia machine, Dialysis machine, Ultrasound machine, MRI machine, CT-scan machine etc., shall not be authorized via special importation route. Product registration is required.

An application for importation of unregistered medical devices should be accompanied by a letter stating reasons for importation. An import permit will be issued if the following criteria are complied with:-

a) Medical device or in vitro diagnostic has been approved by IMDRF founding member countries (Japan, Australia, Canada, Europe and United States of America) or prequalified by WHO;

b) Evidence that a medical device is in circulation in the manufacturer's country of origin (Free Sales Certificate);

c) Declaration of Conformity (certificate of conformity from the manufacturer);

d) Certificate of compliance of the manufacturer to ISO 13485;

Failure to submit any of the above documents shall render the application invalid and shall be rejected.

1.7. Importation of medical devices for personal use

A person may import without holding an importers license as required under section 17 of the Tanzania Medicines and Medical Devices Act, Cap 219, any medical devices for his personal use or the personal use of any member of his family subject to condition and quantity recommended by a registered medical practitioner, dentist or any other authorized practitioner and as the Authority deems fit.

a) Applications for importation of class B, C and D medical devices for personal use, should be accompanied by a written recommendation from a registered medical practitioner, dentist, any other authorized practitioner.

b) Applications for importation of medical devices for personal use should also be submitted along with a letter giving reasons for importation from applicant or qualified medical practitioner, dentist, or any other authorized practitioner.

1.8. Importation medical devices including laboratory equipment for clinical trial purposes

Application for importation of medical devices including laboratory equipment should be accompanied by the valid ethical clearance certificate issued by the recognized institution.

The application should be made by a clinical trial sponsor or Principal Investigator for a study approved to be conducted in Tanzania Mainland. Such applications should be accompanied by clinical trial ethics approval letter and copy of certificate of clinical trial issued by TMDA.

1.9. Importation of Spare parts of medical devices including laboratory equipment

Application for importation of spare parts of medical devices including laboratory equipment shall be accompanied by the letter stating reasons for importation and the following;

a) A contract of preventive and corrective maintenance between the supplier and the facility (where applicable);

b) A letter from the facility stating the need of such spare part (where applicable);

c) Proof of availability of machines in the Tanzania Mainland.

1.10. Importation of consumables and accessories

Application for importation of consumables and accessories should be accompanied with the evidence of existence of main device on the market.

1.11. Inspection of imported consignments at ports of entry

a) On arrival at the ports of entry, medical devices and in vitro diagnostics will be inspected by TMDA Inspector to ensure that they comply with the approved specifications and regulations before they are released.

b) Each consignment must be accompanied by an import permit, an original proforma invoice and airway bill or bill of lading.

c) Other government agencies may also conduct inspection activities as the rules and regulations apply. Such agencies may include Tanzania Revenue Authority (TRA) or other authorized agents.

d) At the time of importation, medical devices and in vitro diagnostics must have a valid shelf life not less than 60 % of the original shelf life (where applicable).

1.12. Sampling of imported products

a) TMDA will sample imported medical devices for further investigation when deemed necessary. The sample collection form **Annex II** will be used during sampling which will be signed in duplicate by TMDA inspector and the consignee and one copy will be issued to the later.

b) Investigation or consultation may take some time before they are concluded, especially where it involves laboratory analysis of the consignment. Where such cases arise, a conditional release will be given to the importer with instructions to store the consignment in approved premises until results of the investigations are out.

c) It is important to note that laboratory analysis normally takes a period of twenty one (21) days from the time a consignment is sampled to when the results are released. The time mentioned above applies only if the laboratory analysis is to be done at TMDA Laboratory. Where analysis is to be carried out outside TMDA, a longer period may be required.

d) Sampling for high risk medical devices and in vitro diagnostics will be carried out on every lot of the consignment. TMDA shall from time to time prescribed the list of items which to which this pre-distribution requirement is mandatory.

1.13. During inspection of the consignment the following actions may be taken:-

a) An approval for release;

b) A query may arise whereby the consignment may be held at customs warehouse or owner's premises pending further investigation;

c) An outright rejection of the consignment pending re-exportation or destruction at owner's expenses.

1.14. Authorized Ports of Entry (PoE)

All medical devices as well as in vitro diagnostics imported into Tanzania would be allowed to enter through the following official ports of entery (POEs):

Air	Sea/Lake	Land
1. Julius Nyerere International Airport	1. Dar es Salaam sea port	1. Namanga
2. Kilimanjaro International Airport	2. Tanga sea port	2. Tunduma
3. Mwanza Airport	3. Mtwara sea port	3. Holili
4. Songwe Airport	4. Lindi sea port	4. Sirari
5. Kigoma Airport	5. Bagamoyo sea port	5. Horohoro
	6. Mwanza lake port	6. Tarakea
	7. Bukoba lake port	7. Kasumulu
	8. Kigoma lake port	8. Manyovu
	9. Musoma lake port	9. Mutukula
	10. Rusumo falls port	10. Kabanga
	11. Itungi lake port	11. Kilambo
	12. Kassesya lake port	12. Mtambaswala
	13. Kemondo bay port	13. Isaka dry port
	14. Kipili lake port	14. Kasanga
	15. Mbambabay port	15. Mabamba
	16. Kilwa Masoko port	16. Murongo
	17. Mafia port	17. Kogaja
		18. Ikola
		19. Kabwe

The Authority reserves the final decision in authorizing importation of medical devices and in vitro diagnostis through any other PoEs other than those indicated above.

1.15. Release or rejection of a consignment

(i) Conditions for release of a consignment:

a) All approved consignments will be released by TMDA Inspector once satisfied that all importation conditions have been fulfilled.

b) An Inspector will stamp all the supporting documents with an official stamp marked **"APPROVED FOR RELEASE"**.

c) In case of partial shipment a consignment will be issued with one import permit which can be used in three divided shipments and an inspector will clearly mark in the original permit and profoma invoice that it is "**PARTIAL SHIPMENT**" and the quantity imported and remaining will be indicated in the profoma invoice and permit.

(ii) Conditions for not releasing the consignment

a) Consignments which do not meet importation requirements will be rejected by TMDA and the accompanied documents shall be stamped with an official stamp marked **"STOP RELEASE";**

b) Medical devices and diagnostics rejected for quality reasons will be **CONDEMNED;**

c) Medical devices and diagnostics rejected because of being unregistered in Tanzania or with generic labeling, upon application ***may*** be re-exported to a third country ***on special request*** and ***with special clearance from the Regulatory Authority*** of the country where the consignment is being exported to;

d) A re-export exercise should be preceded by re-inspection of the rejected consignment to confirm that it is still intact before re-export permit is issued by TMDA;

e) Re-loading for re-export should be witnessed by Customs officials and Inspector(s) from TMDA;

f) Copies of re-export documents stamped at the exit port shall be submitted to TMDA as evidence of completion of re-exportation exercise;

g) Destruction of rejected medical devices and diagnostics will be done as per the Customs requirements and TMDA will provide technical advice on mode of destruction according to the guidelines for disposal of unfit medical devices and diagnostics;

h) TMDA will issue a Destruction Certificate after completion of the destruction exercise;

i) Where the consignment is rejected/detained, TMDA Inspector will issue a Rejection/Detain Form of medical device consignment(s) as specified under **Annex III** of these guidelines.

2. CHAPTER TWO

IMPORTATION OF DONATED MEDICAL DEVICES INCLUDING LABORATORY EQUIPMENT

2.1. Scope of Application

The procedures outlined below will be applicable to all donated medical devices, in vitro diagnostics and laboratory equipment.

2.2. Principle

1. *All Donations will be in accordance with the recipient's need and should comply with the existing government policies, laws, guidelines and administrative arrangements.*

2. *Donation should comply with applicable standards and there will not be double standards regarding quality of donated items. Unacceptable medical devices, in vitro diagnostics and laboratory equipment in the donor country shall not be allowed into the recipient's country.*

2.3. Requirements for Donation

2.3.1. General Requirements

2.3.1.1 Any person, institution and organization intending to donate medical devices will be required to apply for import permit through TMDA Online portal (tmda.go.tz/portal) as prescribed under Section 1.3.1 of these guidelines **prior to shipment** of the donated consignment.

2.3.1.2 Application should be accompanied by the following documents:-

a) A support letter from the relevant authority which supports such donation (where applicable);

b) A support letter from the importer;

c) Donation certificate;

d) Declaration of Conformity of donated medical devices or diagnostics from manufacturer/donor/certified company (where applicable);

e) Proforma invoice;

f) certificate of analysis for sterile medical devices, in vitro diagnostics and laboratory equipment (where applicable);

g) certificate of refurbishment for used medical devices (issued by manufacturer/donor of certified company);

h) Certificates from relevant authorities for specific device such as Tanzania Atomic Energy Commission (TAEC).

2.3.1.3 The Authority will assess if the medical device, in vitro diagnostic and laboratory equipment is compatible with the recipient.

2.3.1.4 Medical devices, in vitro diagnostics and laboratory equipment intended to be donated must be collected as much as possible from known sources for ease of traceability.

2.3.1.5 Donated medical device, in vitro diagnostic and laboratory equipment should have a shelf life of not less than 60% of the original shelf life (where applicable).

2.3.1.6 If the medical device, in vitro diagnostic and laboratory equipment is used, it must be reconditioned, tested and all essential parts, accessories and working materials included before shipment together with the relevant supporting documents to indicate that the device is in good order.

2.3.1.7 Donated medical devices, in vitro diagnostics and laboratory equipment shall:-

a) be robust and fully operational as a full system or as a separate subsystem;

b) Meet or exceed existing safety and performance specifications provided by the manufacturer, international or appropriate national standards;

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

d) have its label, user manual and other documents written in English or Swahili;

e) be packed in the manner that is suitable for road, air or sea transport under tropical conditions.

2.3.1.8 For software operated medical devices and diagnostics, the software shall be either preloaded and/or accompanied by the software package.

2.3.1.9 For electrical equipment, the electrical needs of the equipment shall be set to the standard voltage of 220V/50Hz to 240V/50Hz and for X-ray emitting equipment that it shall be calibrated and inspected by a qualified Medical Physicist.

2.3.1.10 Damaged, outmoded, and redundant medical devices and diagnostics for which spare parts and consumables are no longer available shall not be accepted.

2.3.1.11 The Authority will issue Donation import permit when satisfied that all conditions of application have been fulfilled; otherwise the application will be rejected in writing through TMDA online portal by stating the reason for rejection.

2.3.1.12 The permit issued for importation of donated medical devices, in vitro diagnostics and laboratory equipment will be valid for six months.

2.3.2.Requirements at the Port of Entry

Donated medical devices, in vitro diagnostics and laboratory equipment shall have port clearance from the Authority and shall be accompanied by the following documentary evidences:-

a) Valid import permit;

b) Packing list;

c) Commercial invoice;

d) Airway bill /bill of lading;

e) Disinfected or decontaminated.

2.3.3. Label of the donated medical device, in vitro diagnostic and laboratory equipment

Depending on its nature and type, the label of donated medical device, in vitro diagnostic or laboratory equipment should have the following minimum information:-

a) The name of the medical device, in vitro diagnostic or laboratory equipment;

b) Model number or serial number;

c) Manufacturing and expiry dates; (where applicable)

d) Life span or expectancy;

e) Name and address of the manufacturer;

f) Handling and storage requirement(s);

g) Technical direction for use;

h) An indication, if applicable, that the medical device, in vitro diagnostic or laboratory equipment is intended to be used

i) The words "used only for clinical or performance investigations" before being supplied;

j) For a sterile medical device, the word "Sterile" and where appropriate, description of methods of re-sterilization;

k) If it is a refurbished device or laboratory equipment, an indication that the device or laboratory equipment is refurbished;

l) If the device is intended for presentation or demonstration purposes only, it must be labeled as "for presentation or demonstration purposes only, not for use on human";

m) If the device emits radiation for medical purpose, details of its nature, type and where appropriate, the intensity and distribution of the respective radiation;

n) If the device is to be installed with or connected to other medical device, in vitro diagnostic or laboratory equipment, or with dedicated software, in order to operate as required for its intended use, sufficient details of its characteristics to identify the correct device or equipment to use in order to obtain a safe combination;

o) If the device is an in vitro diagnostic device it must be labeled as " in vitro diagnostic" or "IVD";

p) The intended purpose of the medical device, in vitro diagnostic or laboratory equipment, the intended user of the device, and the kind of patient on whom the device is intended to be used (if this information is not obvious);

q) Any number, letter or symbol, and any letter or number in a symbol, used in the label shall be legible.

Each donated medical device, in vitro diagnostic or laboratory equipment shall have accompanying user manual having detailed information on handling, installation, operation, maintenance, trouble shooting, precautions and other important information.

Donated medical devices, in vitro diagnostics or laboratory equipment shall be transported, stored and handled in accordance with acceptable transportation, storage and handling requirements.

Labeling information of the medical device, in vitro diagnostic and laboratory equipment can be provided on the device itself, packaging used for the device, on an Insert supplied with the device or in a printed document or using other appropriate media.

At the time of importation, medical devices, in vitro diagnostics and laboratory equipment must have a valid shelf life not less than 60 % of the original shelf life (if applicable).

2.3.4.Reporting

The recipient will be required to report relevant information to the Authority including defects, adverse effects, problems related to quality and safety and other reportable cases related to the donated equipment prior to the use or as soon as the same is discovered.

2.3.5. Disposal

If donated medical device, in vitro diagnostic and laboratory equipment are found to be unfit, the recipient shall dispose or return the product to the country of origin at his/her own expenses.

3. CHAPTER THREE

EXPORTATION OF MEDICAL DEVICES

3.1. Exporters of medical devices

Exporters of medical devices, in vitro diagnostics and laboratory equipment fall under the following categories:

a) Registered local devices manufacturers;

b) Registered wholesalers;

c) Clinical trial sponsors and investigators;

d) Persons authorized by TMDA.

3.2. Requirements for exporters

a) No person shall export devices out of the country without a valid export permit issued by the Authority.

b) All devices to be exported must originate from a registered manufacturer or wholesaler in Tanzania Mainland.

c) All exporters must export devices through authorized PoEs or as determined by TMDA.

d) Devices intended to be exported should either be registered or authorized by TMDA.

3.3. Procedure for exportation of medical devices, in vitro diagnostics and laboratory equipment

Authorized exporter intending to export devices should apply through TMDA online portal (tmda.go.tz/portal).
The application shall be accompanied by one proforma invoice.

Proforma invoices shall state for each device to be exported, the following(s);

a) Invoice Number and date;

b) Name and address of the supplier;

c) Name and address of the importer;

d) Name and address of the manufacturer;

e) Country of origin;

f) Country of destination;

g) Clear description of items including brand and common names as declared in information of devices;

h) The quantity to be exported for each device, its unit value, total value in convertible currency;

i) The product registration number issued by the Authority;

j) Batch or Lot number;

k) Manufacturing and expiring date;

l) Mode of shipment (sea, air, road);

m) Port of exit;

n) Signature and stamp of the supplier and/or manufacturer.

Export permit shall not be transferable and shall be issued to cover only one shipment.

Application for export permit shall be accompanied by a processing fee as prescribed in TMDA Fees and Charges Regulations in force.

After being satisfied by the information submitted, an *Export Permit* will be issued as prescribed under **Annex V** of these guidelines. The permit will be valid for 3 months from the date of issue.

Exporting wholesalers will be required to provide evidence of source of the exported products.

All applications for export will be processed within 24 hours on working days.

Applications for export permit must be submitted and approval obtained before shipment of the consignment.

An application will be rejected if it does not meet any of the exportation requirements by stating clearly reason(s) thereof.

4. CHAPTER FOUR

REVIEW AND APPEAL PROCEDURE

4.1 Any person aggrieved by the decision of the Authority in relation to any application for importation or exportation of devices may appeal for review of the decision to the Director General within a period of 14 days from the date of receipt of the decision.

4.2 The Authority may review its decision, reject or vary the condition of approval.

4.3 After reconsideration of the application, if the applicant is not satisfied by the decision of the review, may appeal to the Minister responsible for Health.

ANNEX I

TMDA/DMC/MDC/P/003

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PERMISSION TO IMPORT REGISTERED MEDICAL DEVICES/DIAGNOSTICS/LABORATORY EQUIPMENT

Section 73(1) of Tanzania Medicines and Medical Devices Act, Cap 219

Permit No: ……

PART A:

Name of registered importer.....Postal address .....Tel. No.....

Exporting Country.....Invoice No……

Date.....Time.....

Exporter/Sender..... Postal address.....

Arrival expected by ship/air/motor vehicle, via.....Port of entry

Application for permission to import the following product (s) in accordance with the above mentioned Act and Regulations made

Sn	Name of Product		Product	Quantity to be Imported	Value of product(s)
	Brand name	Common name	Registration No		

TOTAL:

Fees Receipt No Dated

.....

PART B:

Permission is hereby granted to import the above mentioned product(s). The importer has to contact the Port TMDA Inspector to examine the approved product(s) before entry into Tanzania Mainland.

Date **FOR: Director General and stamp**

Prepared By:

.....

PART C:

I _____ being TMDA Inspector at _____ port Office has examined the above listed product(s) and i therefore grant/not grant entry into Tanzania Mainland.

Date SIGNATURE OF TMDA PORT OFFICER AND STAMP

This permit is valid from: _____ to _____ Note:

- The Inspector has to return immediately a completed copy of this permit bearing import stamp to TMDA Zone Manager.

ANNEX II

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

MEDICAL DEVICES/DIAGNOSTICS/LABORATORY EQUIPMENT

POST MARKETING SURVEILLANCE SAMPLING FORM

1. Sample code:.....

(Region/product/sequence number/sampling date (ddmmyy))

2. Name of Premises where sample wastaken:.....

3. Physical Address.....Postal address.....

Telephone No..... .....Fax No.....

Email address. ..... (if applicable)

4. Product name of the sample: .....

5. Strength (if applicable):.....

6. Device type: .....

7. Pack size: .....

8. Batch/lot number:.....Date of manufacture: .....

Expiry date: .....

9. Name and physical address of the manufacturer:

.....

.....

10. Number of units collected.....

11. Comment on storage condition of device at the premises:.....

.....

.....

12. Name and signature of the Representative of the premise where sample was collected:

Name.....Signature.....Date.....

13. Name of Inspector (s)/Sampling officer

S.No	Name	Organization	Signature	Date

Note: Samples should be collected in their original containers.

ANNEX III

...../DMC/...../SOP/.....

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

REJECTION/RETENTION OF MEDICAL DEVICE/DIAGNOSTICS/LABORATORY EQUIPMENT CONSIGNMENT(S)

(*Made under Section 99 (4) of Tanzania Medicines and Medical Devices Act Cap 219*)

Exporter /Consigner ……

Importer/Consignee……

The inspected consignment (s) as per Proforma Invoice No .....Airway Bill No...../Bill of Lading No……/R.Number……..dated.....and the single Bill of Entry Number…….dated….....has been Rejected/Retained for the following reasons:- (Tick whichever applicable)

1. Proforma Invoice is not approved by TMDA ☐
2. Importation fees is not paid to TMDA ☐
3. The products(s) is/are not registered/notified by TMDA ☐
4. Consignee is not an authorized dealer of medical devices/diagnostics ☐
5. Manufacturer of product is not indicated
6. Description of the items is not clear ☐

7. Manufacturing and/expiring date of products (s) not indicated ☐

8. The products (s) shelf life is too short/expired ☐

9. Physical quality of the product is poor ☐

10. Packaging Insert/IFU not included ☐

11. Certificate of analysis not present ☐

12. Batch number not indicated ☐

13. Any other ..... (Specify)

Comments from the Inspector if any.....

.....

…….……..	…….	……..
Name of Inspector	Signature	Date
……..……..	…….	……..
Full name of consignee/ Clearing agent	Signature	Date

ANNEX V

TMDA/DMC/MDC/P/004

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

EXPORT PERMIT

(Made under Section 73(1) of Tanzania Medicines and Medical Devices Act, Cap 219)

Export Permit No:

PART A: PARTICULARS OF EXPORTER

Name of Exporter _____, Postal Address _____Tel. No _____.

Importing Country _____, Invoice No _____, Date _____. Exporter/Receiver _____, Postal Address _____. Mode of Transport (i.e. ship, air or motor vehicle), via _____ Port of Exit.

S/n	Name of product(s)	Quantity	Quantity Value of Product(s)
TOTAL:			

PART B:

Permission is hereby granted to export the above mentioned product(s). The exporter has to contact the Port TMDA Inspector to examine the approved product(s) before exit outside Tanzania Mainland.

_____

Date

_____

FOR: Director General and stamp

Prepared By:

.....

PART C: DECLARATION BY TMDA INSPECTOR

I _____ being TMDA Inspector at _____ port office has examined the above listed product(s) and i therefore grant/not grant exit outside Tanzania Mainland.

_____ _____

Date SIGNATURE OF TMDA PORT OFFICER AND STAMP

This permit is valid from: _____ to _____

Note: • The Inspector has to return immediately a completed copy of this permit bearing export stamp to TMDA Zone Manager.