*Doc #: TMDA/DMC/MCIE/G/010*

*Rev #: 02*

**TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY**

# GUIDELINES FOR DEALING IN CONTROLLED DRUGS

**Third Edition**

**January, 2021**

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**ABBREVIATIONS**

| | |
|---|---|
| API | Active Pharmaceutical Ingredient |
| BP | British Pharmacopoeia |
| CoA | Certificate of Analysis |
| DCEA | Drug Control and Enforcement Authority |
| FoC | Free of Charge Goods |
| GCLA | Government Chemist Laboratory Authority |
| GMP | Good Manufacturing Practices |
| RIMS | Integrated Regulatory Information Management System |
| INCB | International Narcotics Control Board |
| INN | International Non-proprietary Name |
| LPO | Local Purchase Order |
| LTR | Local Technical Representative |
| MSD | Medical Stores Department |
| NEMC | National Environment Management Council |
| NGOs | Non-Government Organizations |
| NMRA | National Medicines Regulatory Authority |
| OGDs | Other Government Departments |
| PI | Principal Investigator |
| PoE | Ports of Entry |
| QAP | Quality Assurance Program |
| TBS | Tanzania Bureau of Standards |
| TFDA | Tanzania Food and Drugs Authority |
| TMDA | Tanzania Medicines and Medical Devices Authority |
| TRA | Tanzania Revenue Authority |
| USP | United States Pharmacopoeia |
| PEN | Pre Export Notification |

## ACKNOWLEDGEMENTS

These guidelines were reviewed and developed in order to update dealers in controlled drugs with relevant information on requirements for handling controlled drugs. I wish to take this opportunity on behalf of TMDA to thank all those who in one way or another assisted in the review of the previous edition.

A debt of gratitude is specially owed to the following TMDA staff who worked diligently and tirelessly towards reviewing and finalizing these guidelines:-

- Mr. Emmanuel Alphonce - Medicines and Complementary Products Inspection and Enforcement Section
- Mr. Damas Matiko - Planning, Monitoring and EvaluationSection
- Dr. Henry Irunde - Zone Offices and Local Government Coordination
- Ms. Sonia Mkumbwa - Central Zone Office
- Ms. Doreen Nyaki - Medicines and Complementary Products Inspection and Enforcement Section
- Ms. Gloria Matemu - Eastern Zone Office
- Ms. Chimpaye Julius - Medicines and Complementary Products Inspectionand Enforcement Section

- Mr. Paul Sonda - Medicines and Complementary Products Inspection and Enforcement Section
- Mr. Selemani Justine - Medicines and Complementary Products Inspection and Enforcement Section
- Ms. Catherine Bruno - Medicines and Complementary Products Inspection and Enforcement Section
- Mr. Faustine Masatu - Medicines and Complementary Products Inspection and Enforcement Section
- Ms. Joyce Komba - Directorate, Medical Products Control

The valuable inputs received from TMDA esteemed stakeholders namely Pharmaceutical Industries, Healthcare Providers and Professionals, Government and Non-Government Institutions are greatly acknowledged.

Last but not least the TMDA Management is acknowledged for constructive comments and inputs during deliberations and final approval of these guidelines.

Amsallah
Akida M. Khea
Acting Director, Medical Products Control

## FOREWORD

Tanzania Medicines and Medical Devices Authority (TMDA) was established under the Tanzania Medicines and Medical Devices Act, Cap 219 to ensure quality, safety and effectiveness of medicines, medical devices and diagnostics.

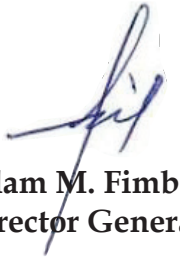
The Authority has established a system to regulate among other things, importation, exportation, manufacture, storage and distribution of controlled drugs in Tanzania. For proper handling of application for importation of controlled drugs, clear and appropriate information is important for our stakeholders and these guidelines are meant to serve this purpose. The control measures included in the guidelines are based on recommendations by the International Narcotics Control Board (INCB) so as to prevent diversion of controlled drugs from licit to illicit use.

The first and second editions of these guidelines for dealing in controlled drugs were developed in 2003 and 2015 respectively. The third edition has accommodated the recent legal changes made through Finance Act, No.8 of 2019 whereby the regulation of food and cosmetics has been transferred to Tanzania Bureau of Standards (TBS) and the name of the Authority was changed from TFDA to TMDA. The review was necessited by the need to streamline services delivery within TMDA.

This edition has catered for on line procedures for importation and exportation of controlled drugs which can now be accessed through TMDA online trader portal. The requirements and procedures for inspection of controlled drugs at the ports of entry (PoE), manufacturing, stocking, distribution, disposal, record keeping and reporting, handling for the loss, review and appeal procedures have been clearly defined. Furthermore, the guidelines have included new procedures for importation of controlled drugs in a state of

emergency such as disease outbreaks, natural disasters and accidents.

It is anticipated that dealers in controlled drugs will familiarize with these guidelines and make use of it as guidance on proper handling of these drugs and limit their use only for medical and scientific purposes. Any comments or inputs that will improve these guidelines in future are highly welcome.



**Adam M. Fimbo**
**Director General**

## DEFINITION OF TERMS

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

**Act**
Means the Tanzania Medicines and Medical Devices Act, Cap 219;

**Authority**
Means the Tanzania Medicines and Medical Devices Authority, or its acronym "TMDA";

**Authorized Personnel**
Means any person other than registered pharmaceutical personnel authorized to dispense controlled drugs;

**Authorized Prescriber**
Means any person other than registered medical practitioner, dentist or veterinarian authorized to prescribe controlled drugs;

**Consignment**
Means one shipment of goods which an import permit was issued

**Consumption**
Means when a drug has been supplied to any person or hospital, enterprises for retail distribution, medical use or scientific research;

**Container**
Means a bottle, jar, box, sachet, or other receptacle which contains or is to contain in it, not being a capsule or other article in which the product is or is to be administered or eaten, and, where any such receptacle is to be contained in another such receptacle, includes the former but does not include the latter receptacle;

**Controlled drugs**
Means any narcotic drug, psychotropic substance and precursor as described under section 77(2) of the Act;

**Dealer in controlled drugs**
Means a person who carries on directly or otherwise the business of buying, selling, supplying, manufacturing and distributing controlled drugs;

**Dispense**
Means supply of a drug product on and in accordance with a prescription lawfully given by medical practitioner, dentist or veterinarian;

**Export Permit**
Means a permit issued to exporter by the Authority, authorizing him to export controlled drugs or raw materials from the country;

**Exporter**
Means a person or institution authorized to export controlled drugs or raw materials to any other country;

**Illicit traffic**
Means cultivation, importation or distribution of controlled drugs contrary to the provision of the law;

**Importer**
Means a person or institution authorized to import controlled drugs or raw materials into the country;

**Import permit**
Means a permit issued to importer by the Authority, authorizing him to import controlled drugs or raw materials into the country;

**Inspector**
Means TMDA inspector appointed, authorized or recognized under Section 105 of the Act;

**International Drug Control Conventions** Means:

(a) The Single Convention on Narcotic Drug 1961 adopted by the United nations conference in New York in March 1961

(b) The protocol amending the Convention mentioned is sub clause (a) adopted by United Nations Conference in Geneva in March 1972.

(c) The Convention on Psychotropic substances, 1971 adopted by the United Nations conference at Vienna on 19/12/1988.

(d) Any other international drug control convention or protocol or other instrument amending an international Drug Convention relating to narcotic drugs, precursors or psychotropic substances which may be ratified or acceded to by the United Republic of Tanzania.

**International Narcotics Control Board (INCB)**
Means, the United Nations organ established by the 1961 Single Convection on narcotic drugs, which in collaboration with governments limits the cultivation, production, manufacture and use of controlled drugs to an adequate amount required for medical and scientific purposes;

**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 pharmaceutical product or raw material;

**Manufacture**
Means all operations involved in the preparation, processing, compounding, formulating, filling, refining, transformation, packaging, repackaging and labeling of products;

**Manufacturer**
Means a company that carries out operations such as production, packaging, repackaging, labeling and re-labeling of controlled drugs or raw materials;

**Narcotic drugs**
Means any of the substances, natural or synthetic in schedule I and II of the Single convection on narcotic drug, 1961 and that convention as amending the single convention on narcotic drugs and provided in the *Tanzania Food, Drug and Cosmetics (Scheduling of Medicines) Regulations, 2015 Schedule 1A, Annex 1 & 2;*

**Online Trader Portal**
Means customer online self-service portal available at TMDA website.

**Packaging materials**
Means, any material, including printed material, employed in the packaging of a pharmaceutical, but excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product;

**Precursors**
Means, substances frequently used in the manufacture of narcotic drugs or psychotropic substances as provided for under the International Drug Control Conventions;

**Prescription**
Means lawfully written direction by a medical practitioner, dentist, veterinary surgeon or any other authorized prescriber for the preparation and dispensing of drugs by a pharmacist or authorized dispenser;

**Psychotropic substances**
Means any substance, natural or synthetic or any natural material in schedule I, II, III and IV of the Convention on Psychotropic Substances, 1971 and provided for in the *Tanzania Food, Drugs and Cosmetics (Scheduling of Medicines) Regulations, 2015 Schedule IA, Annex 3 & 4.*

**Raw materials**
Means any substance of a defined quality used in the production of controlled drugs, but excluding packaging materials;

**Stock**
Means a drug that has been supplied to any person or hospital, enterprises for retail distribution;

**Superintendent**
Means Pharmacist in charge who supervises a pharmacy business and registered as such under the Pharmacy Act, Cap 311 or Veterinarian who is registered under the Veterinary Act, Cap 319;

**Unfit Controlled Drugs**
Means products which violets any provision of the Act.

## 1.0 INTRODUCTION

Tanzania Medicines and Medical Devices Authority is an institution under Ministry of Health, Community Development, Gender, Elderly and Children which has been mandated to control quality, safety and efficacy of Medicines, Medical Devices and Diagnostics.

Section 78 of the Tanzania Medicines and Medical Devices Act, Cap 219 has provided legal framework for the Authority to control controlled drugs in the country. These drugs are not ordinary pharmaceuticals despite being used in a variety of settings by healthcare practitioners and by people who are prescribed to manage their condition(s). Based on that, they should be closely regulated and subjected to strict legal controls as they are susceptible to being misused or diverted and can cause harm to patients or individuals.

In view of this context, the review of these guidelines have an objective of providing importers, distributors, healthcare facilities, healthcare workers and users with requirements and guidance to ensure they are properly managed and used safely as per legal frameworks governing their intended use.

These guidelines have been organized into six (6) major sections as follows:-

(a) First section provides guidance on importation of controlled drugs;
(b) Second section explains exportation of controlled drugs;
(c) Third section outlines review and appeal procedures;
(d) Fourth section describes stocking and distribution of controlled drugs;
(e) Fifth section provide guidance on record keeping and reporting;
(f) Sixth section provides guidance on disposal and handling of loss;

This guidance is expected to provide robust governance arrangements for monitoring the safety and effective use of controlled drugs that encourage good practice as well as to detect

unusual or poor clinical practice systems, criminal activity or risk to patients. Safe governance principles should be applied to all healthcare settings and individual practices where controlled drugs are prescribed, supplied, stored, administered or transported.

It is anticipated that adherence to these guidelines by all stakeholders including healthcare workers, law enforcers and general public will contribute substantially in preventing, detecting, and responding to diversion of controlled substances.

## 2.0 IMPORTATION OF CONTROLLED DRUGS

### 2.1 Categories of importers for Controlled Drugs and Raw Materials

2.1.1 Importers of controlled drugs shall fall under the following categories:-

a) Government and Non- Governmental Institutions;
b) Pharmaceutical Importing Wholesalers;
c) Pharmaceutical Manufacturers;
d) Clinical Trial Sponsors and Principal Investigators;
e) Recipients of Donations; and
f) Any other person authorized by Authority for medical and scientific purposes

2.1.2 Notwithstanding with 2.1.1 above, importation of narcotics for human consumption shall be solely done by Medical Stores Department (MSD)

### 2.2 General requirements for importers of Controlled Drugs

2.2.1 All importers must be registered by TMDA unless given special approval by the Authority.

2.2.2 All importers should import controlled drugs through authorized Ports of Entry (PoE) as outlined under 2.8 of these guidelines.

2.2.3 In case of donations, importers must have a donation certificate and adhere to the Guidelines for Donations issued by the Ministry responsible for Health. The donated controlled drugs must be fit for human consumption, good quality, safe and not prohibited in the country of origin.

2.2.4 A person shall not import any controlled drugs with shelf life of more than 24 months whose remaining shelf life is less than 60% or a controlled drugs with shelf life of less or equal to 24 months whose remaining shelf life is less than 80%.

2.2.5 All imported controlled drugs should adhere to the following labeling requirements:-

a) Information printed on labels must be indelible or engraved or embossed on a primary and secondary container;
b) Immediate outer packaging of the controlled drugs should be clearly labeled in English or Swahili language or both;
c) Trade or brand name where appropriate should be stated;
d) International Non-Proprietary Name (INN, Generic name) shall be clearly stated;
e) Quantities of Active Pharmaceutical Ingredients (API) and excipients in the formulation should be stated;
f) Manufacturing and expiry dates should be stated;
g) Batch or Lot number should be stated;
h) Pack size should be stated;
i) Storage conditions should be stated;
j) Name and address of manufacturer should be stated;
k) Registration number of the product issued by TMDA in both outer and inner package of the product(s) should be stated;
l) Enclosed and accompanying literatures must be written in English or Swahili language; and
m) API pharmacopoeial specification such as BP and USP should be stated.

2.2.6 In case of imported raw materials for manufacturing of finished pharmaceutical products, the following labeling requirements should be adhered to:-

a) Information printed on labels must be visible and indelible;
b) Immediate outer packaging of the raw material labeled in English;
c) Generic name of the ingredient and pharmacopoeial specification stated;
d) Manufacturing and expiry dates;
e) Batch or Lot number;
f) Storage conditions;
g) Name and address of manufacturer; and
h) Weight and Volume where applicable

## 2.3 Procedure for importation of controlled drugs

2.3.1 All importers should have online access to the online trader portal available in the TMDA website www.tmda.go.tz by using *trader account* issued by TMDA upon filling in a customer online access registration form (**TMDA/DBS/ICT/F/001**) whose template is attached as **Annex I** to these guidelines.

2.3.2 Customer online access application forms shall be available in TMDA website www.tmda.go.tz.

2.3.3 All applications shall be made through *online trader portal* and accompanied with uploaded scanned copies of the proforma invoice, valid TMDA business permit and covering letter for issuance of Certificate of Official Approval of Import of Controlled Drugs.

a) The proforma invoice(s) for controlled drugs to be imported shall state each of the following (s);
b) Profoma invoice number and date;
c) Name of the supplier;
d) Name of the manufacturer;
e) Country of origin;
f) Trade or Brand name;
g) The International Non Proprietary Name (INN) of the API and its strength;
h) In case of product containing more than one API, the INN and strength of each shall be stated;
i) The pharmacopoeial specifications of the API such as BP, USP;
j) The product registration number issued by the TMDA where applicable;
k) The quantity to be imported for each product, pack size, unit value, total value and acceptance currency;
l) Batch number for each product if available;
m) Manufacturing and expiry dates;
n) Mode of shipment (sea, air, road);
o) Destination port of entry;
p) Signature and stamp of the supplier;
q) Name and signature of Superintendent; and
r) Importer's signature and stamp.

2.3.4 In case of raw materials, proforma invoice(s) shall state each of the following (s):-
a) Proforma invoice number and date;
b) Name of product;
c) Name and address of the supplier;
d) Name and address of the manufacturer;
e) Country of origin;
f) The API pharmacopoeial specifications;
g) The quantity to be imported for each raw material, pack size, unit value, total value and acceptance currency;

h) Batch/Lot number;
i) Manufacturing and expiry dates;
j) Mode of shipment (sea, air, road);
k) Destination port of entry;
l) Signature and stamp of the supplier;
m) Name and signature of Superintendent; and
n) Importer's signature and stamp.

2.3.5 Applications must be submitted at least 30 days before the arrival of the consignment to avoid delays in processing import applications.

## 2.4 Processing of applications for importation of Controlled Drugs and Raw Materials

2.4.1 Upon receiving the applications for importation of controlled drugs, TMDA will scrutinize to verify whether the requirements have been fulfilled.

2.4.2 If the application meets the prescribed requirements, the applicant will be required to pay import fee as stipulated in the Fees and Charges Regulations in force, and the Authority will issue an online import permit (**TMDA/DMC/MCIE/P/004**) whose template is as set out in the **Annex II** of these guidelines.

2.4.3 In case of application not complying with the prescribed requirements, the Authority shall issue online query(s) to the applicant for rectification before further processing or reject right away.

2.4.4 Upon receiving query response, the Authority shall re-process application and if satisfied issue import permit online. In case of dissatisfaction, the Authority shall reject

the application and communicate with applicant by letter or online clearly stating reason(s) for rejection.

2.4.5 In case of approved application, all applicants shall be accountable to print the import permits online and collect from TMDA offices Certificate of Official Approval of Import of Controlled Drugs whose templates is as set out as **Annex III** of these guidelines.

2.4.6 The certificate of official approval of import of controlled drugs shall be valid for nine (9) months, whereby certificate for importation of narcotics drugs will be printed in yellow colored paper while for psychotropic substances will be in pink colored paper.

2.4.7 Import permit shall be valid for nine (9) months from date of issuance, not transferable and issued to cover only one shipment. However, in case of partial shipments, only three shipments may be allowed based on the initial import permit within validity of the initial permit.

2.4.8 The Authority upon request from the applicant may extend not more than one time the validity of the issued import permit if satisfied with reasons given by the applicant.

2.4.9 Application for extension of the permits for importation of controlled drugs shall be made prior to its expiry and the maximum period for extension given shall not exceed three (3) months.

2.4.10 All applications will be processed within one day (24 hours) with exception of special requests which shall be processed within seven (7) working days.

## 2.5 Requirements for special importation of controlled drugs

The same application requirements and procedures as prescribed under 2.2 and 2.3 respectively shall apply. However, special importation permit may be issued under the following circumstances:-

### 2.5.1 Importation of unregistered controlled drugs

Permit for importation of unregistered controlled drugs may be issued if the following requirements have been complied: -

a) The applicant has uploaded covering letter stating reasons for importing such medicines and Certificate of Analysis (CoA) for each product to be imported;
b) In case of request to import products for health facilities the applicant has in addition uploaded supporting letter and Local Purchase Order (LPO) from the respective facility;
c) In case of request to import products for veterinary use, the applicant has in addition uploaded a supporting letter from the Ministry responsible for Livestock;
d) The product(s) to be imported has no registered therapeutic equivalent (alternative) products;
e) The product(s) to be imported is manufactured from TMDA approved GMP facility or approved by TMDA based on other criteria; and
f) The product(s) has registered therapeutic equivalent, but proven by TMDA not to have been imported for a minimum period of six (6) months.

### 2.5.2 Importation of controlled drugs for personal use

Permit for importation of controlled drugs for personal use may be issued if the following requirements have been complied: -

a) Application has been accompanied by a prescription from a registered medical practitioner, dentist, veterinarian or any other authorized practitioner;
b) Application has been accompanied with a letter giving reasons for importation of pharmaceuticals for personal use as may be requested by the Authority;
c) Application has been accompanied with a current medical report from a reputable hospital
d) In case of patients under treatment with preparations containing internationally controlled drugs are entering the country or leaving the country with acceptable quantity of such preparations for personal use. When entering the country the following conditions must be fulfilled:

    i. The traveler must hold prescription written by the registered practitioner. The prescription should be written in English language and indicate:-
        a) A name of patient, name of medicinal products (trade and INN), posology and total amount of medical preparation prescribed.
        b) Treatment duration which has to be not more than 30 days. Prolongation of treatment if needed should be obtained within the country.

ii. If the quantity of the preparation exceed the internationally recommended limit traveler should apply to TMDA for import permit.
iii. Narcotic drugs included in schedule IV of the 1961 Convection are not allowed to be carried by travelers even if they are permitted in the country of departure.
iv. Preparations intended for personal use of narcotics drugs listed in schedule III of the 1961 Convention may be carried without restrictions; and
v. Type and quantity prescribed must comply with country of origin, country of destination and / or international requirements.

e) When leaving the country travelers should comply with aforementioned sections (i) – (v), regulations of the country of destination and international requirements.

### 2.5.3 Importation of investigational controlled drugs

Permit for importation of investigational controlled drugs may be issued if the Authority is satisfied that, the application has been made by the Clinical Trial Sponsor or Principal Investigator for the study approved to be conducted in Tanzania Mainland. Such application shall be accompanied by clinical trial approval letter issued by TMDA.

### 2.5.4 Importation of Free of Charge Goods (FoC)

a) All free of charge goods shall be charged as per Fees and Charges Regulations in force.
b) The profoma invoice of free of charge goods shall meet the requirements indicated at 2.3.3 above.

### 2.5.5 Importation of samples for registration

Importation of samples for registration shall meet the following criteria:-

a) The proforma invoice meets the requirements indicated in 2.3.3 and clearly state "*samples for registration purposes only*".
b) The unit pack should not exceed five (5), unless approved by the Authority.

### 2.5.6 Importation of controlled drugs in a state of emergency

In emergency situations such as during earthquakes, floods, hurricanes, epidemics, conflicts or displacement of populations where the Authority may be unavailable to process import permit for controlled drugs in a timely manner to meet the situation, the following procedures may be followed:-

a) Operator shall submit to the supplier for emergency supplies of controlled substances.

b) Operator shall be responsible for:-
   i. Actual handling of drugs at the receiving end or adequate delivery to the reliable recipient;
   ii. Reporting to the Authority on unused quantities, if any, when operator is the end user or to arrange for the end user to do so;
   iii. Reporting to the control authorities of the exporting country through the supplier, with copy to INCB, any problem encountered in the working of emergency deliveries.

c) Upon being satisfied that the nature of emergency justifies application of the simplified procedure without import permit, the supplier shall:-
   i. Submit a copy of shipment request to the controlling Authority of the exporting country;
   ii. Submit an annual report on emergency deliveries and quantities of drugs involved as well as their destinations, with copy to INCB;
   iii. Report to the control Authority of the exporting country with copy to the INCB, any problem encountered in the working of emergency deliveries.

d) The control authorities of the exporting country shall inform the Authority (whenever they are available) of the emergency deliveries and the Authority shall have the right to refuse the importation of such deliveries.

e) Emergency deliveries shall not be included in the country estimates as they are regarded as having being consumed in the exporting country.

## 2.6 Controlled Drugs exempted from importation charges

Notwithstanding the requirements prescribed in these guidelines, the following items are exempted from TMDA importation charges:-

a) Packaging and raw materials;
b) Controlled drugs for personal use;
c) Investigational controlled drugs;
d) Samples for registration;
e) Controlled drugs for laboratory use; and
f) Any other product as may be approved by the Authority.

## 2.7 Inspection of imported consignments at ports of entry

a) On arrival at the ports of entry, consignments of controlled drugs and raw materials shall be inspected by TMDA inspector to ensure that they comply with the requirements of these guidelines before being allowed entry into the country.

b) Each imported consignment must be accompanied by an import permit, original proforma invoice, commercial invoice, airway bill/bill of lading/ road consignment note, CoA for each batch and original certificate of official approval of import of controlled drugs endorsed by exporting country.

c) Other Government Departments (OGDs) such as Tanzania Revenue Authority (TRA), Tanzania Bureau of Standards (TBS), Drugs Control and Enforcement Authority (DCEA) and Government Chemist Laboratory Authority (GCLA) may also inspect these consignments as per their rules and regulations.

d) During inspection, the inspector may collect suspicious samples for further investigation.

e) Inspectors shall be duty bound to ensure that records for all imported controlled drugs and raw materials are maintained in the available Regulatory Management Information System (RMIS).

### 2.7.1 Sampling of imported products

a) Sampling of imported controlled drugs and raw materials shall be conducted using sample collection form TMDA/DMC/F/007 whose

template is attached as **Annex IV**. The form shall be signed in duplicate by TMDA inspector and consignee with a copy issued to the consignee.

b) Import samples may be collected at the PoE or at owner's warehouse/premises when necessary.

c) Investigations on suspicious samples collected may take some time before they are concluded, especially if it involves laboratory analysis of the product(s). Where such case arises, a conditional release may be given to the importer with instruction to store the consignment in approved premises until results of the investigation has been released and communicated officially to the consignee.

### 2.7.2 Action to be taken on inspected consignments

The following action may be taken by an inspector after conducting inspection:-

a) Approval for release or entry into the country;
b) Detain the consignment at customs bonded warehouse or owner's premises pending further investigation; and
c) Reject the consignment and order re-exportation or destruction at owner's costs.

## 2.8 Authorized Ports of Entry (PoE)

Controlled drugs imported into Tanzania Mainland would be allowed entry into the country through the following authorized PoE:

a) Julius Nyerere International Airport,
b) Dar es Salaam Sea Port,
c) Kilimanjaro International Airport,

d) Horohoro,
e) Holili,
f) Namanga,
g) Sirari,
h) Tunduma,
i) Mtukula Kyaka,
j) Any other port prescribed by the Authority

## 2.9 Release or rejection of consignments

### 2.9.1 Conditions for release of consignments:-

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

b) The inspector will stamp on the original import permit and all other supporting documents with an official stamp marked **"APPROVED FOR RELEASE"**;

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

### 2.9.2 Conditions for rejection of consignments:

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) Consignments rejected for quality reasons shall be condemned and order for destruction issued;

c) Destruction of rejected consignments will be done as per the Act and its Regulations in force.

d) Consignments rejected for being unregistered in Tanzania or neutral labeling **may** be re-exported to the country of origin, or re –exported to a third part country **on special request and** certificate of official approval of import of controlled drug **from the National Medicines Regulatory Authority (NMRA)** of the country where the consignment is being re-exported;

e) TMDA shall officially inform the Customs departments for re-exportation of the consignment;

f) Re-export exercise should be preceded by re-inspection of the rejected consignment to confirm that it is still intact before export permit **TMDA/DMC/MCIE/P/004** whose template is attached as **Annex V** to these guidelines is issued by TMDA;

g) Re-loading for re-export should be supervised and witnessed by Customs officials, TMDA Inspector(s) and other law enforcing agencies;

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

i) Where the consignment is rejected/detained inspector will issue a Seizure/ Rejection Form TMDA/DMC/F/004 whose template is provided as **Annex VI** to these guidelines.

## 3.0 EXPORTATION OF CONTROLLED DRUGS

### 3.1 Categories of exporters for controlled drugs and raw materials

3.1.1 Exporters of controlled drugs fall under the following categories:-

a) Registered Domestic Pharmaceutical Manufacturers;
b) Registered Importers;
c) Clinical Trial Sponsors and Investigators; and
d) Any other person authorized by the Authority.

### 3.2 Requirements for exporters

3.2.1 A person shall not export controlled drugs and raw materials without having a valid export permit issued by the Authority.

3.2.2 Export of controlled drugs and raw materials should be through the authorized PoE. (refer 2.8 aforementioned)

3.2.3 All exporters who intend to export controlled drugs and raw materials of which they are not registrants or LTR shall be required to obtain a *no objection letter* from the

registrants or LTR or manufacturer in case of domestic products.

3.2.4 In case of applicants who intend to export personal use medicines, a valid prescription from a registered medical practitioner, dentist, veterinarian or any other authorized practitioner should be provided to the Authority by the applicant and its authenticity proved.

### 3.3 Procedure for exportation of controlled drugs

3.3.1 All exporters should have online access to the trader portal available in the TMDA website www.tmda.go.tz by using trader account issued by TMDA upon filling in customer online access registration form **TMDA/DBS/ICT/F/001** whose template is attached as **Annex I**.

3.3.2 Customer online access application forms shall be available in TMDA website www.tmda.go.tz.

3.3.3 All applications shall be made through *online trader portal* and accompanied with uploaded scanned copies of the proforma invoice and valid TMDA business permit. The applicant will be required to submit to TMDA original certificate of official approval of import of controlled drug from NMRA of the importing country.

3.3.4 The proforma invoice(s) shall state each of the following (s);

a) Proforma invoice number and date;
b) Name and address of the exporter;
c) Country of destination;
d) Trade or Brand name;

e) The INN of the API and its strength;
f) In the case of the product containing more than one API, the name and strength of each shall be stated;
g) The pharmacopoeial specifications of the API such as BP and USP;
h) The quantity to be exported for each pharmaceutical product or raw material; pack size, unit value, total value and currency;
i) Batch/Lot number for each product;
j) Manufacturing and expiry dates;
k) Mode of shipment (sea, air, road);
l) Port of exit; and
m) Bear stamp and signed by a pharmacist or veterinarian of the exporting company.

**3.4 Processing of applications for Exportation of Controlled drugs and Raw Materials**

3.4.1 Upon receiving the applications for exportation, TMDA will scrutinize to verify whether the requirements have been fulfilled.

3.4.2 If the application meets the prescribed requirements, the Authority will issue an export permit whose template is as set out in the **Annex V** of these guidelines.

3.4.3 In case of application not complying with the prescribed requirements, the Authority shall issue online query(s) to the applicant for response before further processing or reject out right.

3.4.4 Upon receiving query response, the Authority shall re-process application and if satisfied issue export permit online. In case of dissatisfaction,

the Authority shall reject the application and communicate with applicant online or by letter stating clearly reason(s) for rejection.

3.4.5 In case of approved applications, it shall be the responsibility of the applicant to print the export permit online and proceed with clearance of consignment at port of exit.

3.4.6 Export permit shall be valid for six (6) months from date of issuance, not transferable and issued to cover only one shipment. However, in case of partial shipments, only three shipments may be allowed based on the initial export permit, within validity of the initial permit.

3.4.7 The Authority upon request from the applicant, may extend not more than one time the validity of the issued export permit if satisfied with reasons given by the applicant.

3.4.8 Application for extension of the export permits shall be made prior to its expiry and maximum period for extension given shall not exceed three (3) months.

3.4.9 All applications will be processed within one day (24 hours) with exception of special requests which shall be processed within seven (7) working days.

3.4.10 Export permits will be issued after verification and the same shall be reported to importing country through INCB web-portal PEN-ONLINE

3.4.11 Export permits issued by TMDA will not attract any charges.

## 4.0 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 controlled drugs and raw materials 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.

4.4 The decision of Minister responsible for Health shall be final and conclusive.

## 5.0 STOCKING AND DISTRIBUTION OF CONTROLLED DRUGS

5.1 Facilities authorized to stock and distribute controlled drugs:

a) Government and Non- Governmental Institutions;
b) Pharmaceutical Importing Wholesalers;
c) Pharmaceutical Manufacturers;
d) Pharmaceutical Wholesalers, Retailer and Distributors; and
e) Any other authorized person by Authority.

Note: MSD shall be the sole distributor of narcotic drugs for human use to Health facilities authorized by TMDA.

## 5.2 Requirements for stocking controlled drugs in authorized facilities

Facilities stocking controlled drugs shall comply to the following requirements;

a) Should have registered pharmaceutical personnel or any other authorized personnel;
b) Should have a well secured storage area under lock and key such as cupboard, safe and strong room;
c) In case of stocking narcotics, the facility should be providing services which require the use of narcotics such as palliative care, surgical procedures and wildlife immobilization;
d) Should have a register or ledger for recording entry and issuance;
e) Storage conditions should abide to requirements provided in the Tanzania Food, Drugs and Cosmetics (Registration of Premises, Importation and Exportation of Pharmaceutical Products and Raw Materials) Regulations, 2015 and its guidelines; *and*
f) In case of opiod substitution medicated substance (Methadone), additional stocking requirements shall abide to the *Guidelines for Procurement, Storage, Distribution and Dispensing of Methadone* issued by DCEA.

## 5.3 Procedures for procurement of controlled drugs

5.3.1 Any authorized dealer may procure psychotropic substances and precursors from any authorized importer, distributor or wholesaler.

5.3.2 Patients shall procure psychotropic substances from retail pharmacies upon producing a valid prescription from a registered medical practitioner, dentist, veterinarian or any other authorized prescriber.

5.3.3 In case of procurement and use of narcotics from MSD, the applicant shall adhere to the following procedures;

a) Apply to TMDA through form P01/DMC/MCIE/G/010 of which the template is attached as **Annex VII**.
b) The duly filled in, signed and stamped application form shall be accompanied by the following:-
    i. One (1) recent passport size photograph of registered pharmaceutical personnel/ authorized persons who shall be the in-charge of narcotic drugs; together with
    ii. Certified copy of registration certificate of the registered/ authorized person.
    iii. Covering letter from the facility introducing the registered pharmaceutical personnel or authorized person

Note: Attachment mentioned under (i) - (iii) shall only apply for first time applicants and in case of change of the pharmaceutical personnel in charge.

c) The application form should state the type of drug, strength and estimated quantity to be consumed for a period of twelve months;
d) In case of new applications, inspection of the respective facility shall be conducted to check compliance with regards to storage requirements and use

as per narcotics drugs checklist for public/private hospital inspection checklist whose template is attached as **Annex VIII** to these guidelines;

e) After meeting all the requirements the Authority shall issue a Hospital Permit for Use of Narcotic Drugs of which template is attached as **Annex IX**;
f) The permit shall expire on 31st December of each calendar year and may be suspended or revoked by the Authority in case of violation of requirements; and
g) In case of requirement for additional quantity of narcotic drugs to meet unexpected demand, the applicant may with justification re-apply for additional quantities to meet the demand within the same year.

## 5.4 Dispensing of controlled drugs

### 5.4.1 Personnel authorized to dispense controlled drugs

Only registered pharmaceutical personnel or any authorized medical personnel shall dispense controlled drugs pursuant to a valid written prescription signed by a registered medical practitioner/dentist/veterinarian or any other authorized prescriber.

### 5.4.2 Content of prescription for controlled drugs

A prescription may be generated manually or electronically and shall have the following contents:-

a) Serial number;
b) Name, level, registration number and address of health facility;

c) Patient's name, age, sex, body weight and physical address;
d) Generic name of the drug, dosage form, strength and dosage;
e) Name, quantity, strength and dosage form of drug(s);
f) Complete directions for use;
g) Date of prescription and dispensing dates;
h) Bear stamp or official seal of the health facility from which it is prescribed;
i) Contain only one type o f drug;
j) Dispenser's name, designation, registration and telephone numbers and signature;
k) Prescriber's name, designation, registration and telephone numbers and signature;
l) Period of supply; and
m) Any other dispensing condition as the prescriber may specify.

5.4.3 A prescription containing narcotic drug shall not be honored after time lapsing of seven days from the date of issue.

5.4.4 Controlled drug(s) needed in a situation where written prescription cannot reasonably be obtained it may be considered as an emergency situation, in such case pharmaceutical personnel or any other authorized personnel may dispense a drug pursuant to verbal prescription from a registered prescriber.

5.4.5 A prescription given under 5.4.4 shall be put in writing immediately by the pharmaceutical personnel and shall specify quantity of medication sufficient for the emergency period not exceeding 24 hours.

5.4.6 Within seven (7) days of the receipt of verbal prescription for a controlled drug the pharmaceutical personnel shall obtain a prescription signed by the prescribing practitioner for the medication dispensed. This prescription shall be attached to the copy of the prescription prepared by the pharmaceutical personnel or authorized personnel pursuant to the prescriber's verbal order.

5.4.7 Dispensing of Methadone will be done as directed in the *Guidelines for Procurement, Storage, Distribution and Dispensing of Methadone* issued by DCEA

## 6.0 RECORD KEEPING AND REPORTING

### 6.1 Record keeping

6.1.1 Every facility shall keep complete and accurate records of the acquisition and disposition of all controlled drugs. Such records shall be maintained electronically or manually or both for a period not less than five (5) years. These records shall include:-

a) Complete and accurate records of receipt of all controlled drugs;
b) Complete and accurate consumption records of all controlled drugs;
c) Complete and accurate records of disposal of all controlled drugs.

6.1.2 All records pertaining to controlled drugs shall be made available for inspection by inspectors. These records shall be maintained in such a manner that they are readily retrievable from other documents.

6.1.3 In case of facility to be closed permanently, the facility in charge shall notify the Authority in writing within ninety days (90) and provide information or details to whom the controlled drugs were transferred or disposed of.

6.1.4 Facilities which suspend or stop procurement and use of controlled drugs shall notify the Authority officially.

6.1.5 Narcotic drugs received and issued shall be recorded in a narcotic drug ledger book (s) TMDA/DMC/MCIE/R/003 whose template is attached as **Annex X**.

6.1.6 Narcotic drugs shall be ordered from the designated store controlled by the pharmaceutical personnel or any other authorized custodian of the facility in small quantities for use in hospital wards and theatre provided that these are kept in a securely locked container or area.

6.1.7 Amount received shall be recorded in red ink and amount issued shall be recorded in blue or black ink.

6.1.8 Any error in record entry in ledger books shall be cancelled once and signed thereon.

6.1.9 Psychotropic substances and precursor chemicals received and issued shall be recorded in a controlled drugs ledger.

**6.2 Reporting**

6.2.1 Narcotic consumption and estimate reports

a) MSD shall furnish to the Authority consumption estimates of the following year by February of each year

b) All health facilities authorized to procure and use narcotic drugs shall be required to furnish to the Authority the following reports:-

i. Quarterly consumption reports by 15th of April, July, October and January

ii. Annual consumption reports by 15th January of the next calendar year; and

iii. Consumption estimates for the coming year by 15th January of the next calendar year

6.2.2 All manufacturers dealing with raw materials shall be required to furnish to the Authority quarterly and annual consumption reports by 15th of April, July, October and January

## 7.0 DISPOSAL AND HANDLING LOSS OF CONTROLLED DRUGS

### 7.1 Disposal of Controlled Drugs

Destruction of unfit controlled drugs will be under the direct supervision of TMDA. The procedure for disposal shall be as per regulations and guidelines in force.

### 7.2 Handling Loss of Controlled Drugs

In an event of loss of controlled drugs, a complete inventory of the remaining controlled drugs shall be made within forty eight (48) hours of discovery of loss of controlled drugs. The respective institution shall report the matter to the Police as soon as practicable and to the

Authority immediately after completion of the inventory report.

The report to be sent to Authority shall include the following:-

a) Name and address of the institution or facility;
b) License permit or registration number;
c) Date of when discrepancy was detected;
d) Police Loss Report;
e) Police case number;
f) Total amount lost; and
g) Nature of loss.

## 8.0 ANNEXES

**ANNEX 1: Customer online access registration form**

| TMDA Tanzania Medicines & Medical Devices Authority | ONLINE SERVICES ACCESS REGISTRATION FORM | *TMDA/DBS/ICT/F/001 Rev #:1* |
|---|---|---|

**1. Applicant Details**

a) Company Name: .....

b) TIN No: .....

c) Company Email Address (Valid and active email): .....

d) Telephone: ..... Fax: .....

e) Postal Address: ..... Website: .....

f) Country: ..... Region: .....

g) District: .....

h) *Physical Address: .....

**2. Contact Person /Local Agent Details**

a) Full Name: .....

b) Telephone No: .....Email: .....

c) Country: .....Region: .....

d) Postal and Physical Address: .....

**3.** Tick type of product requested for access

Medicines ( ) Medical Devices ( ) Diagnostics ( )

**4.** I hereby confirm that the above information is true and valid.

Customer Name: ..... Signature: ..... Date.....

**5. Authorization by responsible Section**

Remarks by authorizing Officer

……

Name: _____Signature:_____Date:_____

**ICT Section**

Name: _____Signature:_____Date:_____

**NOTE:** ***Attach copy of TIN Certificate***

**ANNEX II: Permission to import registered product(s)**

**TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY**

Email: info@tmda.go.tz
Fax +255 28 2541484
Website www.tmda.go.tz
Telephone +255 22 2450512/2450751/2452108

Tanzania Medicines and Medical Devices Authority
P.O Box 1253 Dodoma

**TMDA/DMC/MCIE/P/004**

**PERMISSION TO IMPORT REGISTERED MEDICINES**
**(Made under Section 73(1) d of Tanzania Medicines and Medical Devices Act 2003)**
**Permit No : TMDA-WEB……../D/IPER/……..**

**PART A: PARTICULARS OF IMPORTER**

Name of registered importer:……,Postal Address : …… Tel. No.……..
Exporting Country: ……Invoice No…….. Date …… Time…… Exporter/Sender: …… Postal address , ……. Arrival expected by ship, air or motor vehicle via ……. as port of entry.

| | Name of Product | | Product | Quantity to be Imported | Value of the Product |
|---|---|---|---|---|---|
| S/n | Brand Name | Common Name | Registration No | | |
| | | | | | |
| TOTAL (FOB Value) | | | | | |

**PART B: GRANTING PERMISSION**

Permission is hereby **granted** to **import** for 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……..**

Prepared By: …… **FOR:DIRECTOR GENERAL**

**PARTC:DECLARATIONBYTMDAINSPECTOR**

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.

**MISSION:**
To protect and promote public health by ensuring, safety and effectiveness of medicines, medical devices and diagnotics

**ANNEX III: Certificate of official approval of import of controlled drugs**

**FORM A: Import Certificate Issued by the United Republic of Tanzania**

**Serial No. ... ... ... ... ... ... ... ...**
**File No.**

**THE UNITED REPUBLIC OF TANZANIA**
**MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN**

E-mail: Info@tmda.go.tz
Telephone: 255 22 2450512, 2450751
Fax No: 255 22 2450793
All letters should be addressed to the Director General
In reply please quote:

**TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY**
P. O. BOX 1253
Dodoma

**Certificate of Official Approval of Import**
(*Section 78 (1*) Medicines and Medical Devices Act, Cap 219)

I, being the person with the administration of the law relating to Narcotic drugs to which the International Convention on Narcotic drugs apply, hereby certify that I have approved the importation by: -

.....

Of:

.....

From: .....

Subject to conditions that: -

i. the consignment shall be imported before the ..... and

ii. the consignment shall be imported by ..... through .....

and that I am satisfied that the consignment proposed to be imported is required :-
Solely for Medical purposes and scientific purposes: -

.....

.....
Signature and Stamp
Director General, Tanzania Medicines and Medical Devices Authority

This document is solely for production to the Government of the country from which the

**ANNEX IV: Sample Collection Form**

| | | |
|---|---|---|
| TMDA Tanzania Medicines & Medical Devices Authority | **SAMPLE COLLECTION FORM** | **TMDA/DMC/F/007**<br>**Rev #: 0** |

***(Made under Section 101 (1) of TFDCA Cap 219)***

Name of Institution/ Company/PoE ……

Address:
……

Date of collecting sample: …….....

Reasons for collection (Indicate analysis needed where possible)

……

| Sample ref. number | Product Name and strength | Product Description eg. Color, Dosage, etc | Batch No. | Manufacturing date | Expiry Date | Name and Address of Manufacturer | Quantity sampled |
|---|---|---|---|---|---|---|---|
| | | | | | | | |

| **Name of Representative(s) of the Company/ consignment.** | **Signature** | **Date** |
|---|---|---|
| 1. ……..... | …… | …… |
| 2. ……. | …… | …… |

| **Name of TMDA Inspector (s) (Sampling Officer)** | **Signature** | **Date** |
|---|---|---|
| 1. …….. | …… | …….. |
| 2. …….. | …… | …… |

**ANNEX V : Permission to Export Product(s)**

**TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY**


Email: info@tmda.go.tz

Fax +255 28 2541484

Website www.tmda.go.tz

Telephone +255 22 2450512/2450751/2452108

Tanzania Medicines and Medical Devices Authority
P.O Box 1253 Dodoma


**TMDA/DMC/MCIE/P/004**

**PERMISSION TO EXPORT MEDICINES**
**(Made under Section 73(1) d of Tanzania Medicines and Medical Devices Act 2003)**
**Permit No : TMDA-WEB……../D/XPER/……..**

**PART A: PARTICULARS OF EXPORTER**

Name of registered exporter:……,Postal Address : …… Tel.No……..
Exporting/Importing Country: ……..Invoice No…….. Date …… Time……
Sender/Receiver:……Postal address,……
Arrival expected by ship, air or motor vehicle via …… as port of entry.

| | Name of Product | | Product | Quantity to be Imported | Value of the Product |
|---|---|---|---|---|---|
| S/n | Brand Name | Common Name | Registration No | | |
| | | | | | |
| TOTAL (FOB Value) | | | | | |

**PART B: GRANTING PERMISSION**

Permission is hereby **granted** to **export** for the above mentioned product(s).
The importer has to contact the Port TMDA Inspector to examine the approved product(s) before EXPORT To Tanzania Mainland.
**Date……..**

Prepared By: …… **FOR:DIRECTOR GENERAL**

**PARTC:DECLARATIONBYTMDAINSPECTOR**

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.

**MISSION:**
To protect and promote public health by ensuring, safety and effectiveness of medicines, medical devices and diagnostics

**ANNEX VI: Seizure/Rejection Form**

| | | |
|---|---|---|
| TMDA Tanzania Medicines & Medical Devices Authority | **SEIZURE/REJECTION FORM FOR PRODUCTS CONSIGNMENT AT PORT OF ENTRY** | **TMDA/DMC/F/004 Rev #: 00** |

***(Made under Section 99 (4) of TFDCA Cap 219)***

1. Importer/Exporter: ……
2. The inspected consignment(s) as per Proforma Invoice No.: ……
3. Airway Bill No.: ……/Bill of Lading No……
4. R. Number: …….. Dated: ……
5. TANSAD Number: …… Dated: ……
6. Has been detained/rejected for the following reasons: - *(Tick whichever applicable)*

a) TMDA Importation permit is not present ☐

b) The product(s) is/are not registered by TMDA (where applicable) ☐

c) Consignee is unauthorized dealer of the product(s) being imported ☐

d) Manufacturer of the product(s) is not indicated ☐

e) Description of the items is not clear ☐

f) Manufacturing and/ expiring date of product (s) not indicated ☐

g) The product (s) shelf life is too short/expired ☐

h) Physical quality of the product is poor ☐

i) Packaging insert/IFU not included ☐

j) Certificate of Analysis (CoA) not present and/or results of the tests on CoA do not comply with specifications ☐

k) Batch/ Lot number (s) not indicated ☐

l) Any other (Specify) ……

Inspector's comments if any ……

| | | |
|---|---|---|
| …… | …… | …… |
| Name of TMDA Inspector | Signature | Date |
| ……..…… | …… | …… |
| Name of Consignee/Clearing Agent | Signature | Date |

**ANNEX VII: Application for Procurement and Use of Narcotic Drugs**

| TMDA Tanzania Medicines & Medical Devices Authority | **APPLICATION FOR PROCUREMENT AND USE OF NARCOTIC DRUGS** | *TMDA/DMC/MCIE/F/012* *Rev #: 01* |
|---|---|---|

Director General,
Tanzania Medicines and Medical Devices Authority,
P. O. Box 1253
DODOMA

| |
|---|
| Name of Hospital: |
| Registration Number: |
| Postal address: |
| Physical address: |
| Name of the Medical Officer in charge/superintendent:<br><br>Dr …… Registration……..…… |
| The drugs will be under control of Pharmacist in charge:<br><br>Name …… Profession ……..……<br><br>Indicate registration number …….. |
| Attach Pharmacist In-charge photograph: |
| I/We do hereby apply to procure and use the following narcotic drugs:<br><br>Name of narcotic drug: Annual estimate:<br>1……. ……<br>2……. ……<br>3……. ……<br>4……. …… |
| Name of the Medical Officer In charge……..<br><br>Signature …… Date …….. |

**ANNEX VIII: Narcotic Drug Checklist for Public / Private Hospital / Pharmacy**

| TMDA Tanzania Medicines & Medical Devices Authority | **NARCOTIC DRUG CHECKLIST FOR PUBLIC/PRIVATE HOSPITAL/PHARMACY** | *TMDA/DMC/MCIE/C/002* *Rev #: 01* |
|---|---|---|

1. Name of hospital…… Reg.no……
2. Address……
3. Location……
4. Name of Proprietor……
5. Doctor In-charge of the hospital……

6. Name of the person in-charge of narcotic drugs: -
   a) Pharmacist…… Reg.no……
   b) Pharmaceutical technician…… Enrollment no……
   c) Others (Nurse)…… ……

7. Name of Matron in-charge of the hospital……

8. Total number of beds in the hospital……
   a) Maternity (Labor) ward……
   b) Orthopedic ……
   c) Surgical ward……
   d) Obstetrician Gynecology ward……
   e) Medical ward……
   f) ENT ward……
   g) Pediatric ward……
   h) Out Patient Department/ Emergency……
   i) Other wards……..

9. Estimated consumption of narcotic drugs per month
   a) Pethidine inj. 100mg/2ml……
   b) Pethidine inj 50mg/ml……
   c) Morphine HCl inj……
   d) Others dosage for: -……

10. Source of procurement of the narcotic drugs: -
    a) Medical Stores Department (MSD) ☐
    b) Others (mention) ☐

11. How are the narcotic drugs stored
    a) Presence of narcotic room……Yes/ No
    b) Presence of DDA…….. Yes/ No
    c) Stored under lock and key…… Yes/No
    d) Others (mention)……Yes/No

12. Inventory control of narcotic drugs
    a) Presence of Ledger book…… Yes/No
    b) Well instituted……Yes/No
    c) Poorly managed…… Yes/ No
    d) Other (mention)…… Yes/No

| Name | Quantity |
|---|---|
| …… | …….. |

14. Quantities issued to:

| Wards | Quantity |
|---|---|
| …… | ……... |
| Theatre | Quantity |
| …….. | …….. |
| Sub-store | Quantity |
| …… | ……... |
| By Prescription | Quantity |
| …… | ……... |

15. Are prescription stored under lock and key……...Yes/No

16. Do records of quantities received and quantities issued tally Yes/ No

17. Are orders signed by authorized personnel…….Yes/ No

18. How are the empty ampoules destructed: -

Crushing……..……

Others (mention)……..……..

General observation ……..
……..

19. Recommendation
……..

Declaration
I ……In charge/owner of the said Hospital, certified that, the information provided is correct.

In charge/owners signature……. Date……

| Name of Drug inspectors | Signature |
|---|---|
| 1 …… | …… |
| 2 …… | …… |
| 3 …… | …… |

Date of Inspection ……..……..

**ANNEX IX: Hospital Permit for Use of Narcotic Drugs**

| TMDA Tanzania Medicines & Medical Devices Authority | HOSPITAL PERMIT FOR USE OF NARCOTIC DRUGS | TMDA/DMC/MCIE/P/001 Rev #: 01 |
|---|---|---|

Ref.No: ..... Date .....

HOSPITAL PERMIT FOR USE OF NARCOTIC DRUGS

Name of the institution: .....

Address: .....

Hospital Registration No: .....

Situated at: .....

Name of Pharmacist In-charge: .....

Is hereby authorized to purchase the following narcotic(s) from Medical Stores Department (MSD) for hospital uses only.

| S/N | Name, dosage form, & strength | Unit of measure | Quantity authorized for this year ..... | Authorized quantity for this permit | The remaining balance for this year |
|---|---|---|---|---|---|
| 1. | | | | | |
| 2. | | | | | |

The validity of this permit expires on 31-December-yyyy

..... .....

**Date** **FOR: DIRECTOR GENERAL**
**TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY**

**Note:**

***The quarterly report of Narcotic drug consumption should be submitted to the Director General Tanzania Medicines and Medical Devices Authority.Annual consumption estimates should be submitted before the end of April every year.***

**ANNEX X: Narcotic Drugs Ledger Book**

| TMDA Tanzania Medicines & Medical Devices Authority | **NARCOTIC DRUGS LEDGER BOOK**<br><br>**Record of used Narcotic drugs in a facility** | *TMDA/DMC/MCIE/R/003*<br>*Rev #: 01* |
|---|---|---|

Name of Health Institution ……..

Address: P. O. Box……Tel ……

Name and Strength of Narcotic drug …….

Serial/Page Number ……

| Date | Received from | Quantity received | GRN | Issued to | Quantity issued | Requisition No. | Remaining Balance | Name & Signature of Receiving Officer | Remarks |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |
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# ABBREVIATIONS


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