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TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

GUIDELINES FOR IMPORTATION AND EXPORTATION OF PHARMACEUTICAL PRODUCTS AND RAW MATERIALS

Fourth Edition

January, 2021

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ABBREVIATIONS

API	Active Pharmaceutical Ingredient
ARVs	Antiretrovirals
BP	British Pharmacopoeia
CoA	Certificate of Analysis
FoB	Free on Board
FoC	Free of Charge Goods
GCLA	Government Chemist Laboratory Authority
GMP	Good Manufacturing Practice
iRIMS	Integrated Regulatory Information Management System
INCB	International Narcotics Control Board
INN	International Non-proprietary Name
LPO	Local Purchase Order
LTR	Local Technical Representative
MoF	Ministry of Finance
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
TMDA	Tanzania Medicines and Medical Devices Authority
TRA	Tanzania Revenue Authority
USP	United States Pharmacopoeia

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- Mr. Emmanuel Alphonce - Medicines and Complementary Products Inspection and Enforcement Section
- Ms. Grace M. Shimwela - Quality Control and Risk Management Unit
- Ms. Rosemary Aaron - Medical Devices and Diagnostics Control Section
- Adv. Ms. Donesta Simon - Eastern Zone Office
- Ms. Estella Meena - Medicines and Complementary Products Inspection and Enforcement Section
- Ms. Aziza Sengo - Medicines and Complementary Products Inspection and Enforcement Section
- Ms. Siya Ringo - Medicines and Complementary Products Inspection Enforcement Section
- Dr. Daniel Fussi - Eastern Zone Office
- Ms. Joyce Komba - Directorate of Medical Products Control

I would like to thank the entire review team for working hard to produce this fourth edition which has been aligned with the TMDA overall objective of improving efficiency in provision of services to our esteemed customers through use of internet services.

Special gratitude are owed to our stakeholders who dedicated their precious time despite busy schedules to give their inputs while reviewing these guidelines.

Last but not least, the TMDA management is acknowledged for constructive comments and guidance during deliberations and 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 with the mission of protecting and promoting public health by ensuring quality, safety and effectiveness of medicines, medical devices and diagnostics.

In view of unique nature of medicines and raw materials used in their manufacturing, the Act requires that any product or person dealing with importation and exportation of medicinal products must be registered by TMDA. These are the fundamental requirements for authorizing importation and exportation of medicinal products into or outside the Tanzania market.

TMDA developed the first guidelines for importation and exportation of pharmaceuticals in the year 2005 which have been progressively reviewed in order to cope with the new developments. The aim of these guidelines is to provide guidance to dealers of pharmaceuticals, inspectors and other stakeholders on information and documentation required during application and clearance of pharmaceutical products and raw materials into or from the country.

Revision of the third edition was necessitated by legal changes which were done through amendment of the Finance Act, No. 8 of 2019 which apart from transferring the regulation of food and cosmetics to TBS also led to change of name of the Authority from TFDA to TMDA. The revision was also necessitated by the need to align the guidelines with current approach of issuance of most services at TMDA through online portal. This edition provides guidance for submission of applications for importation and exportation through online trader portal which is available via TMDA website.

Applicants are urged to familiarize with these guidelines and follow them when preparing and submitting applications

for importation and exportation of pharmaceuticals and raw materials. Adherence to these guidelines will ensure timely submission and processing of applications and avoid unnecessary delays in approval process hence expedite provision of quality services to clients in line with the TMDA Clients Service Charter in force. 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";

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

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 chemicals as described under section 77(2) of the Act;

Export permit
Means a permit issued to exporter by the Authority, authorizing him to export pharmaceutical products or raw materials from the country;

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

Importer
Means a person or institution authorized to import pharmaceutical products or raw materials into the country;

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

Label
Means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on or attached to a container of any pharmaceutical product or raw material;

Manufacturer
Means a company that carries out operations such as production, packaging, repackaging, labelling and re-labelling of pharmaceutical products or raw materials;

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;

Pharmaceutical product
Means a term used interchangeably with the words medicine, pharmaceutical or medicinal preparation or product or therapeutic substance or other article manufactured or prepared in any way and intended for use as a medicine or as a remedy used for the purpose of medical, dental or veterinary treatment;

Prescription
Means a lawful written direction by a medical practitioner, dentist, or veterinarian for the preparation and dispensation of a medicine by pharmaceutical personnel;

Raw materials
Means any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials;

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 No. 16 of 2003;

Online Trader Portal
Means customer online self service portal available in TMDA website.

1.0 INTRODUCTION

Pharmaceutical products and pharmaceutical raw materials are not be treated in the same way as ordinary commodities, hence monitoring of their safety, efficacy and quality from the point of manufacturing throughout the supply chain is essential to protect public health. In view of this context, it is therefore imperative that the importation and exportation of pharmaceutical products and raw materials, be nationally and internationally regulated and conform to set standards.

In view of strengthening the control of importation and exportation of these products for the purpose of preventing entry of substandard, falsified and unregistered products in the country, the Authority has revised these guidelines to cope with the current requirement for effective regulations of medicinal products so as to protect and promote public health. The revised guidelines will also guide our customers on the legal requirements to be adhered during importation and exportation of pharmaceutical products and raw materials.

The main objective of these guidelines is to provide importers and exporters of pharmaceutical products and raw materials with the necessary information to enable them comply with the laws and regulations governing importation and exportation of pharmaceutical products and raw materials into and outside the country.

For that reason these guidelines have been organized in two major parts for importation and exportation of pharmaceutical products and raw materials. The first part provides for the requirements and procedures to be followed during importation of pharmaceutical products and raw materials whilst the second part outlines the requirements and procedures for the exportation of the same. Furthermore, templates of application forms and other relevant documents have been appended for easy referencing.

It is therefore expected that, the use of these guidelines will be one step ahead towards the noble goal of making available pharmaceutical products of acceptable, safety, quality and efficacy to the general public.

2.0 IMPORTATION OF PHARMACEUTICAL PRODUCTS AND RAW MATERIALS

2.1 Categories of importers for pharmaceutical products and raw materials

2.1.1 Importers of pharmaceuticals 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; and
e) Recipients of Donations.

2.1.2 Notwithstanding with 2.1.1 above, the following may be authorized to import pharmaceuticals on special circumstances:-

a) Persons importing pharmaceuticals for personal use;
b) Hospitals importing pharmaceuticals for hospital use;
c) Institutions importing pharmaceuticals for laboratory use; and
d) Importing wholesalers importing unregistered products.

2.2 General requirements for importers

2.2.1 All pharmaceutical products to be imported must be registered by TMDA unless given special approval by the Authority.

2.2.2 Importation of pharmaceutical products and raw materials must be done by importers whose premises are dully registered by TMDA or relevant Government Institutions.

2.2.3 All importers should import pharmaceutical products and raw materials through authorized Ports of Entry (PoE) as outlined under 3.0 of these guidelines.

2.2.4 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 pharmaceutical products must be fit for human consumption, good quality, safe and not prohibited in the country of origin.

2.2.5 A person shall not import any pharmaceutical product with shelf life of more than twenty four months whose remaining shelf life is less than 60% or a pharmaceutical product with shelf life of less or equal to twenty four months whose remaining shelf life is less than 80%.

2.2.6 All imported pharmaceutical products 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 pharmaceutical products 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) should be clearly stated;
e) Quantities of Active Pharmaceutical Ingredients (API) and excipients in the formulation shall be stated;
f) Date of manufacture and expiry should be stated;
g) Batch or Lot number should be stated;
h) Storage conditions should be stated;
i) Name and address of manufacturer should be stated;

j) Registration number of the product issued by TMDA in both outer and inner package of the product(s) should be stated;
k) Enclosed and accompanying literature must be in English or Swahili language;
l) API specification such as BP and USP should be stated.

2.2.7 In case of imported raw materials 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 must be labeled in English;
c) Generic name of the ingredient and pharmacopoeia specification should be stated;
d) Date of manufacture and expiry should be stated;
e) Batch or Lot number should be stated;
f) Storage conditions should be stated;
g) Name and address of manufacturer should be stated;
h) Weight and Volume should be stated

2.3 Procedure for importation of pharmaceutical products and raw materials

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 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 at TMDA offices or 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 and valid TMDA business permit.

2.3.4 The proforma invoice(s) for pharmaceuticals to be imported shall state each of the following (s);

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

2.3.5 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 of the supplier;
d) Name of the manufacturer;
e) Country of origin.
f) The API 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 expiring date;

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

k) Destination port of entry;

l) Signature and stamp of the supplier;

m) Name signature of Superintendent;

n) Importer's signature and stamp.

2.3.6 Applications must be submitted at least 14 days before the arrival of the consignment to avoid delays in processing import applications.

2.4 Processing of Applications for Pharmaceutical Products and Raw Materials

2.4.1 Upon receiving the applications for importation of pharmaceutical products and raw materials, 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 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 Applicant will receive online notification for queried, rejected and approved applications. In case of approved application, the applicant shall be accountable to print the import permit online and proceed with clearance of consignment at port of entry.

2.4.6 Import permit shall be valid for six (6) months from date of TMDA invoice issuance, not transferable and issued to cover only one shipment. However, in case of partial shipments, only two shipments may be allowed based on the initial import permit within validity of the initial permit.

2.4.7 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.

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

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

2.5 Requirements for special importation of pharmaceutical products

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 pharmaceutical products

Permit for importation of unregistered pharmaceutical products 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 to upload an acceptance letter issued by TMDA after receiving a 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;
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 pharmaceuticals for personal use

Pharmaceuticals for personal use shall be imported based on the guidelines for inspection and approval of Medicines and Medical Devices for personal use at PoE.

Permit for importation of pharmaceutical products for personal use which meets the criteria for online application 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) Any bona fide tourist or visitor who enters into or person normally resident who re-enter Tanzania Mainland may bring with him such quantity of any pharmaceutical product as may be required during a period of 21 days for the medical treatment of himself, any member or partner travelling with him.

2.5.3 Importation of investigational medicinal products

Permit for importation of investigational medicinal products 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 has to be accompanied by clinical trial approval letter issued by TMDA.

2.5.4 Importation of controlled drugs (Narcotics and Psychotropics)

Permit for importation of controlled drugs is dealt with in separate guidelines for controlled drugs in force

2.5.5 Importation of Free Medical Samples

Importation of free medical samples shall meet the following criteria:-

a) Samples should bear a label printed "Free sample - Not for sale".

b) Samples should be in a small pack size as compared to commercial pack.
c) The unit pack should be less than 300.

Applications not complying with above criteria will be charged as per Fees and Charges Regulations in force.

2.5.6 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 2.3.4 above.

2.5.7 Importation of samples for registration

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

a) The proforma invoice meets the requirements indicated in 2.3.4 and clearly state "*samples for registration purposes only*".
b) The unit pack should not exceed five (5), unless approved by the Authority.

2.5.8 Importation of pharmaceutical promotional materials

Permits for importation of pharmaceutical promotional materials such as calendars, diaries, t-shirts, fliers, pens, caps, key holders, cups shall be issued if the applicant has attached TMDA approval letter for the promotional materials.

2.5.9 Importation of other medicines

In addition to requirements stipulated under 2.2 and 2.3 above, a letter from applicant should be submitted to TMDA to justify importation of the following:-

a) Pharmaceutical products for emergences e.g. outbreaks, natural disasters and accidents.
b) Pharmaceutical products for specific treatment including cancer.
c) Pharmaceutical products for neglected diseases e.g. Leshmaniasis, Telariasis, Filariasis, Onchoriasis, and Elephantiasis.

2.6 Products exempted from importation charges

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

a) Pharmaceutical raw materials and packaging materials;
b) Pharmaceutical products for personal use;
c) Investigational medicinal products;
d) Free Medical Samples;
e) Samples for registration;
f) Pharmaceutical promotional materials;
g) Pharmaceutical products for laboratory use; and
h) 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 pharmaceutical products and raw materials shall be inspected by a 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 or bill of lading and CoA for each batch. In case of controlled drugs, the consignment shall also be accompanied by a copy of *certificate of official approval of import of controlled drugs*.

c) Other Government Departments (OGDs) such as Tanzania Revenue Authority (TRA), Tanzania Bureau of Standards (TBS), 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 and quality assurance samples such as Antimalarial, Antiretrovirals (ARVs), Anti-tuberculosis and Antibiotics for Quality Assurance Program (QAP) laboratory testing.

e) Inspectors shall be duty bound to ensure that records for all imported pharmaceutical products and raw materials are timely maintained in Regulatory Intergrated Management Information System (RIMS).

2.8 Sampling of imported products

a) Sampling of imported pharmaceutical products and raw materials shall be conducted using sample collection form No. TMDA/DMC/F/007 whose template is attached as **Annex III**. 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 will 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.

2.9 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;
c) Reject the consignment and order re-exportation or destruction at owner's costs.

3.0 AUTHORIZED PORTS OF ENTRY (PoE)

Pharmaceutical products and raw materials imported into Tanzania Mainland would be allowed entry into the country through the following authorized PoEs:

a) Julius Nyerere International Airport,
b) Dar es salaam Sea Port,
c) Kilimanjaro International Airport,
d) Horohoro,
e) Holili,
f) Namanga,
g) Sirari,
h) Mwanza Lake Port,
i) Mwanza Airport,
j) Tanga Sea Port,
k) Tunduma,
l) Mtukula Kyaka,
m) Rusumo Fall Port,
n) Manyovu,
o) Kasumulu,
p) Kabanga

The Authority reserves the final decision in case of importation of pharmaceutical products and raw materials through other PoEs than the above.

4.0 RELEASE OR REJECTION OF CONSIGNMENTS

4.1 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.

4.2 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 TMDA regulations and guidelines of disposal of unfit pharmaceutical products. However, Customs department, NEMC and other law enforcing agencies shall be involved;

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 ***special clearance 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 re-export permit 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 No. TMDA/DMC/F/004 whose template is provided as **Annex IV** to these guidelines.

5.0 EXPORTATION OF PHARMACEUTICAL PRODUCTS AND RAW MATERIALS

5.1 Categories of exporters for pharmaceutical products and raw materials

Exporters of pharmaceuticals fall under the categories:

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

5.2 Requirements for exporters

5.2.1 A person shall not export pharmaceutical products and raw materials without having a valid export permit issued by the Authority.

5.2.2 Export of pharmaceutical products and raw materials should be through the authorized PoE.

5.2.3 All exporters who intend to export pharmaceutical products 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.

5.2.6 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 required.

5.3 Procedure for exportation of pharmaceutical products

5.3.1 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**.

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

5.3.3 All applications shall be made through *online trader portal* and accompanied with uploaded scanned copies of the proforma invoice and valid TMDA business permit.

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

a) Profoma 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, 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 expiring date,
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.

5.3.5 In case of controlled drugs, application shall be accompanied

by certificate of official import approval of controlled drug from the NMRA of an importing country.

5.4 Processing of Applications for Pharmaceutical Products and Raw Materials

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

5.4.2 If the application meets the prescribed requirements, the Authority will issue an export permit **(TMDA/DMC/MCIE/P/004)** whose template is as set out in the **Annex V** of these guidelines.

5.4.3 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.

5.4.4 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.

5.4.5 Applicant will receive online notification for queried, rejected and approved applications. 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 entry.

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

5.4.7 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.

5.4.8 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.

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

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

6.0 REVIEW AND APPEAL PROCEDURE

6.1 Any person aggrieved by the decision of the Authority in relation to any application for importation or exportation of pharmaceutical products 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.

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

6.3 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.

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

7.0 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**

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** 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 III: Sample Collection form

TMDA Tanzania Medicines & Medical Devices Authority	**SAMPLE COLLECTION FORM**	**TMDA/DMC/F/007** **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 e.g. 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 IV: 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 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

SPECIAL PERMISSION TO IMPORT REGISTERED 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 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**

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** 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

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