

TANZANIA FOOD AND DRUGS AUTHORITY



**GUIDELINES FOR IMPORTATION AND EXPORTATION OF PHARMACEUTICAL
PRODUCTS AND RAW MATERIALS**

(Made under Section 73 of the Tanzania Food, Drugs and Cosmetics Act, 2003)

Second Edition

July, 2011

P. O. Box 77150, EPI Mabibo, Off Mandela Road, Dar es Salaam, Tanzania
Tel: +255-22-2450512/2450751/ 2452108; Fax: +255-22-2450793
Email: info@tfda.or.tz; Website: www.tfda.or.tz

TABLE OF CONTENTS

ABBREVIATIONS	III
INTRODUCTION	VI
DEFINITIONS	VII
CHAPTER 1	1
1. IMPORTATION OF PHARMACEUTICAL PRODUCTS AND RAW MATERIALS	1
1.1 CATEGORIES OF IMPORTERS OF PHARMACEUTICAL PRODUCTS AND RAW MATERIALS	1
1.2 REQUIREMENTS FOR IMPORTERS	1
1.3 PROCEDURE FOR IMPORTATION OF PHARMACEUTICAL PRODUCTS	2
1.4 PROCESSING OF APPLICATIONS	3
1.5 SPECIAL IMPORTATION REQUIREMENTS	3
1.6 INSPECTION OF IMPORTED CONSIGNMENTS AT PORTS OF ENTRY	4
CHAPTER 2	7
2.1 EXPORTERS OF PHARMACEUTICAL PRODUCTS	7
2.2 REQUIREMENTS FOR EXPORTERS	7
2.3 PROCEDURE FOR EXPORTATION OF PHARMACEUTICAL PRODUCTS	7
2.4 REVIEW AND APPEAL	8
ANNEX I (Application for importation)	9
ANNEX II (Rejection form)	10
ANNEX III (Permission to import)	11
ANNEX IV (Sample collection form)	12
ANNEX V (Rejection/detention of the consignment)	13
ANNEX VI (Application for exportation)	14
ANNEX VII (Permit to export)	15

ABBREVIATIONS

API	Active Pharmaceutical Ingredient
ARVs	Anti Retroviral drugs
BP	British Pharmacopoes
C&VR	Classification and Valuation Report
COA	Certificate of Analysis
CDO	Central Declaration Officer
FoB	Free on Board
FCVR	Final Clarification and Valuation Report
GMP	Good Manufacturing Practice
HDO	Head Declaration Officer
IDF	Import Declaration Form
MCB	Marine Cargo Booking
MOHSW	Ministry of Health and Social Welfare
MSD	Medical Stores Department
NACP	National Aids Control Program
NGOs	Non-Government Organizations
PoE	Port of Entry
TFDA	Tanzania Food and Drugs Authority
SBE	Single Bill of Entry
TRA	Tanzania Revenue Authority
USP	United States Pharmacopoeia

Acknowledgements

TFDA would like to appreciate the expertise and contribution of the following: Kitundu W.Y.S of MOHSW, Mohamed Jafari of TRA, Robert Mbassa of NACP, Edward Terry of MSD, Martha Kikwale of Morogoro Municipal, Adam M. Fimbo, Emmanuel Alphonse, Adonis Bitegeko, Agnes Kijo, David H. Maganga, Dr. Edgar A. Mahundi, Erasto T. Masha, Lightnes J. Mshana, Donesta Simon, Kissa Mwamwitwa, Aron Elias and Dr. Furaha Nyunza of TFDA. Moreover, the tireless efforts in logistics and secretarial services of Johary Mirambo and Mwanamani Mshana are highly valued.

To a great extent the success and completion of this work was a result of assistance of organizations such as MOHSW, TRA, NACP and MSD which provided technical and material support. Tanzania Food and Drugs Authority (TFDA) would like to thank them collectively as it may not be possible to express its sincere gratitude's to each of them here.

Special thanks should go to the Global Fund for providing financial support that facilitated the development of these guidelines.

Special thanks are also extended to TFDA esteemed stakeholders; the dealers in pharmaceutical industry and in particular members of the Tanzania Association of Pharmaceutical Industry (TAPI), the Tanzania Pharmaceutical Manufacturers Association (TPMA) and religious organizations who discussed the draft guidelines and gave commendable inputs for improving the guidelines.

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

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

Foreword

The Tanzania Food and Drugs Authority (TFDA) was established under the Tanzania Food, Drugs and Cosmetics Act, 2003 with the mission of protecting and promoting public health by ensuring quality, safety and effectiveness of food, drugs, cosmetics and medical devices.

In view of unique nature of pharmaceutical products and its raw materials, the Tanzania Food, Drugs and Cosmetics Act, 2003 provides for control of importation and exportation of pharmaceutical products or any substance used for the manufacture of pharmaceuticals. The law requires that any person dealing with importation of the products must be registered by TFDA and the imported pharmaceutical products must also be registered or approved by the Authority. These are the fundamental requirements for authorizing importation of pharmaceutical products and raw materials into the Tanzanian market.

The first guidelines for importation and exportation of pharmaceuticals were developed by TFDA in the year 2005. The guidelines are therefore reviewed in order to cope with the new developments in terms of requirements for importing or exporting pharmaceutical products and raw materials. The reviewed guidelines currently entitled as "*Guidelines for Importation and Exportation of Pharmaceutical Products and Raw Materials, 2011*" provides for guidance on the information and documentation required in an application submitted to TFDA by an importer or exporter of pharmaceutical products and raw materials.

All applicants are encouraged to familiarize with the guidelines and follow them strictly when preparing and submitting applications for importing or exporting pharmaceutical products and raw materials. Adherence to these guidelines will ensure that all relevant information and documentation are submitted and therefore avoid unnecessary delays in approval process and hence speed up provision of quality services to the clients.

The Authority would like to emphasize that the requirements in these guidelines have been provided to ensure that only safe, efficacious and acceptable quality pharmaceutical products or raw materials are imported or exported. These guidelines will be reviewed from time to time as need arises.

Hiiti B. Sillo
Director General
Tanzania Food & Drugs Authority

INTRODUCTION

The safety, efficacy, and quality of pharmaceutical products can be highly affected by the lack of adequate control on importation and exportation. It is therefore imperative that the manufacture, importation and exportation of pharmaceutical products and raw materials, both nationally and internationally conforms to certain set standards. In view of this context, the importation and exportation of these products should not be treated in the same way as ordinary commodities.

To strengthen the control of importation and exportation of these products, the Authority has revised its guidelines to cope with the current situation. The revised guideline will assist those in field to adhere with the legal framework during importation and exportation activities.

The main objective of these guidelines is to provide importers and exporters of pharmaceuticals with the necessary information to enable them comply with the law and regulations governing importation and exportation of pharmaceutical products and raw materials into and outside the country respectively. These guidelines shall apply to all pharmaceutical products including Antiretrovirals (ARVs), Antitubeculous agents and Antimalarials

For that reason this guideline is organized into two chapters. The first chapter provides for the requirements and procedures to be followed up during importation of pharmaceuticals whilst the second one outlines the requirements and procedures for the exportation of the same. Furthermore, formats 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 that are of safe, efficacious, and acceptable quality, to majority of the people in the country.

DEFINITIONS

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

Authority

Means the Tanzania Food and Drugs Authority, or its acronym "TFDA" established under section 4 (1) of the Tanzania Food, Drugs and Cosmetics Act (TFDCA), 2003

Prescription

Means a lawful written direction by a medical practitioner, dentist, or veterinary surgeon for the preparation and dispensation of a drug by a pharmacist.

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.

Controlled drugs

Means any narcotic drug, psychotropic substance or precursor as described under section 77(2) of the TFDCA, 2003

Certificate

Means a certificate issued by the Authority.

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.

Export Permit

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

Manufacturer

A company that carries out operations such as production, packaging, repackaging, labelling and re-labelling of pharmaceuticals.

Package

Means the package into which the immediate package is placed.

Packaging materials

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/drug

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.

Importer

Means person or institutions authorized to import drugs into the country.

Import permit

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

Raw materials

Any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials.

CHAPTER 1

1. IMPORTATION OF PHARMACEUTICAL PRODUCTS AND RAW MATERIALS

1.1 Categories of importers of pharmaceutical products and raw materials

Importers of pharmaceuticals shall fall under the following categories:

- a) Government and Non- Governmental institutions
- b) Pharmaceutical wholesalers
- c) Pharmaceutical Manufacturers
- d) Clinical trial sponsors and Principal investigators
- e) Recipients of donations

However, the following in the special circumstance can be authorized

- f) Persons authorized to import pharmaceuticals for personal use
- g) Hospitals authorized to import pharmaceuticals for hospital use

1.2 Requirements for importers

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

1.2.2 All importation of pharmaceutical products must be done by importers whose premises are dully registered by TFDA or relevant Government institution.

1.2.3 All importers must import pharmaceutical products through the authorized POE (see section 1.7(4)).

1.2.4 In case of donations, importer must have a donation certificate and adhere to the Guidelines for Donations. The donated pharmaceutical products must be fit for human consumption, safe and of good quality and not prohibited in the country of origin.

1.2.5 No person shall import any pharmaceutical product with shelf life of more than twenty four months whose remaining shelf life is less than 60% and a drug with shelf life of less or equal to twenty four months whose remaining shelf life is less than 80%.

1.2.6 All imported pharmaceutical products should adhere to the following labeling requirements.

- (a) The information printed on labels must be indelible, engraved or embossed on a primary and secondary container;
- (b) The immediate outer packaging of the pharmaceutical products should be clearly labeled in English or Swahili language or both;
- (c) The trade or brand name where appropriate shall be stated;
- (d) The International Non-Proprietary Name (INN, Generic name) shall be clearly stated;
- (e) Quantities of active ingredients in the given formulation/API;
- (f) Date of manufacture and expiry;
- (g) Batch or Lot number;
- (h) Storage conditions;
- (i) Name and address of manufacturer;
- (j) Registration number of the product issued by TFDA in both outer and inner package of the product(s) where applicable;

(k) Enclosed and accompanying literature must be in English or Swahili language;

(l) API specification (BP, USP, etc)

1.3 Procedure for importation of pharmaceutical products

1.3.1 Authorized importer intending to import pharmaceuticals shall apply to the Director General, TFDA by filling in application form as prescribed under **Annex I** of these guidelines.

1.3.2 All applications may be submitted to TFDA head quarter offices or zone offices located in Arusha, Mwanza, Mbeya and Dodoma regions.

1.3.3 The application form shall be accompanied by one original proforma invoice and two (2) copies of original from the marketing authorization holder of the product(s) or authorized supplier(s), subject to provision of the original proforma at the time of importation.

1.3.4 The Proforma invoices shall state for each pharmaceutical to be imported, the following (s);

- (i) Proforma invoice number and date
- (ii) Name of the supplier.
- (iii) Name of the manufacturer.
- (iv) Country of origin.
- (v) Trade or proprietary name.
- (vi) The International Non Proprietary name (generic name) of the drug and its strength.
- (vii) In the case of the product containing more than one active ingredient, the name and strength of each shall be stated.
- (viii) The pharmacopoeial specification of the ingredient such as BP, USP.
- (ix) The product registration number issued by the Tanzania Food and Drugs Authority.
- (x) The quantity to be imported for each drug, its unit value, total value and acceptance currency.
- (xi) Batch number for each product
- (xii) Manufacturing and expiring date
- (xiii) Currency
- (xiv) Mode of shipment (sea, air, road)
- (xv) Destination port of entry
- (xvi) Expected date of arrival
- (xvii) Signature and stamp of the supplier

1.3.5 Application form (Annex I) shall be stamped and signed by the pharmacist or veterinary surgeon in-charge of the importing company before submission to TFDA.

1.3.6 In a situation where section 1.3.5 does not apply, the application form shall be signed by applicant.

1.3.7 Import permit shall be valid for six (6) months, not transferable and issued to cover only one shipment.

1.3.8 In case of partial shipments, only two shipments may be allowed based on the initial import permit.

1.4 Processing of applications

- 1.4.1 Upon receiving the application as specified above, TFDA will scrutinize to verify whether the requirements have been fulfilled.
- 1.4.2 If the application meets the prescribed requirements, the applicant will be required to pay import Free on Board (FoB) fees as stipulated in the Fees and Charges Regulations in force, and the Authority will issue an import permit as set out in the **Annex III** of these guidelines.
- 1.4.3 An application will be rejected if it does not meet any of the importation requirements. An applicant will be given a rejection form (**Annex II**) stating clearly reason(s) for rejection.
- 1.4.4 All applications will be processed within two (2) working days with exception of special requests which may take longer period.
- 1.4.5 All Applications must be submitted at least 21 days before the arrival of the consignment to avoid delays in processing import applications.

1.5 Special importation requirements

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

1.5.1 Importation of unregistered pharmaceutical products

Unregistered pharmaceuticals requested for importation will be issued an import permit only if the following criteria are complied with:-

- a. An applicant has applied for a special permit stating reasons for importing unregistered medicines
- b. The imported pharmaceutical products have no registered therapeutic equivalent (alternative) products available in Tanzania Mainland.
- c. Pharmaceutical products come from a TFDA approved Good Manufacturing practice (GMP) facility.
- d. Pharmaceutical products has registered therapeutic equivalent but proved not to have been imported for a minimum period of 6 months as proved by TFDA.

1.5.2 Importation of medicines for personal use

- i. Applications for importation of medicines for personal use should be accompanied by a prescription from a registered medical practitioner, dentist, veterinary surgeon or any other authorized practitioner.
- ii. Apart from prescription, a letter giving reasons for importation from applicant or qualified medical practitioner, dentist, veterinary surgeon or any other authorized practitioner should also be submitted.

1.5.3 Importation of investigational medicinal products

Applications for importation of investigational medicinal products should be made by a clinical trial sponsor or Principal investigator for a study approved to be conducted in Tanzania Mainland. Such applications should be accompanied by clinical trial approval letter issued by TFDA.

1.5.4 Importation of controlled drugs

- i. Importation permit for controlled drugs shall be issued with additional controlled drugs import certificate which is valid for 6 months.
- ii. Application for controlled drugs import certificate will be processed at TFDA headquarter offices.
- iii. Narcotic drugs will be imported by Medical Stores Department (MSD) only.

1.5.5 Importation of Free Medical Samples

Importation of free medical samples shall meet the following criteria:

- (i) Samples should bear a label printed "Free sample – Not for sale"
- (ii) Samples should be in a small pack size as compared to commercial pack
- (iii) the unit pack should be less than 300

Applications not meeting the above criteria will be charged FoB accordingly.

1.5.6 Importation of Free of Charge Goods (FOC)

- (i) All free of charge goods shall be charged on FoB.
- (ii) The proforma invoice of free of charge goods shall indicate unit price of each product

1.5.7 Importation of other medicines

In addition to requirements stipulated under section 1.2 and 1.3, a letter from an applicant for the following categories of pharmaceutical products should be submitted:

- i. Pharmaceutical products for emergencies e.g. outbreaks, natural disasters and accidents
- ii. Pharmaceutical products for specific treatment including cancer.
- iii. Pharmaceutical products for neglected diseases e.g. Leshmaniasis, Telariasis, Filariasis, Onchoriasis, and Elephantiasis

1.6 Inspection of imported consignments at ports of entry

- (i) On arrival at the ports of entry, pharmaceutical products will be inspected by a TFDA inspector to ensure that they comply with the approved specifications and regulations before they are released. Each batch must be accompanied by an import permit, an original proforma invoice, a corresponding certificate of analysis and airway bill or bill of lading. Other government agencies may also conduct inspection activities as the rules and regulations apply. Such agencies may include Tanzania Revenue Authority (TRA) or other authorized agents. In

case of controlled drugs, the consignment shall be accompanied by a certificate for importation of psychotropic/narcotic drugs.

- (ii) During the process of inspection and release of the consignment, the inspector may sample medicines for further investigations.

1.6.1 Sampling of imported products

- (i) TFDA will sample imported pharmaceutical products and raw materials for further investigation when deemed necessary. The sample collection form **Annex IV** will be used during sampling which will be signed in duplicate by TFDA inspector and consignee and one copy will be issued to the later.
- (ii) Investigation or consultation may take some time before they are concluded, especially where it involves laboratory analysis of the consignment. Where such cases arise, a conditional release will be given to the importer with instruction to store the consignment in approved premises until results of the investigations are out.
- (iii) It is important to note that laboratory analysis normally takes a period of two weeks from the time a consignment is sampled to when the results are released. The time mentioned above applies only if the laboratory analysis is to be done at TFDA Laboratory. Where analysis is to be carried out outside TFDA Laboratory, a longer period may be required.

1.6.2 On inspection of the consignment the following actions may be taken:

- (a) An approval for release may be given.
- (b) A query may arise whereby the consignment may be held at customs warehouse or owner's premises pending further investigation.
- (c) An outright rejection of the consignment pending re-export or destruction at owner's expense may be issued.

1.6.3 Authorized Ports of Entry (PoE)

Medicines imported into Tanzania would be allowed to enter through the following official POEs:

- (i) Dar-es-salaam International Airport,
- (ii) Dar es salaam Sea Port,
- (iii) Kilimanjaro International Airport,
- (iv) Horohoro
- (v) Holili,
- (vi) Namanga,
- (vii) Sirari,
- (viii) Mwanza Lake Port,
- (ix) Mwanza Airport,
- (x) Tanga Sea Port,
- (xi) Tunduma
- (xii) Mtukula

The Authority reserves the final decision in case of importation of medicines through other PoEs than the above PoEs.

1.6.4 Release or rejection of a consignment

A). Conditions for release of consignments:

- i) All approved consignments will be released by TFDA inspector once satisfied that all importation conditions have been fulfilled.
- ii) A drug Inspector will stamp all the supporting documents with an official stamp marked "**APPROVED FOR RELEASE**".
- iii) In case of partial shipment a consignment will be issued one import permit which can be used in two divided shipments and an inspector will clearly mark in the original permit and profoma invoice that it is "**PARTIAL SHIPMENT**" and the quantity imported and remaining will be indicated in the profoma invoice and permit.

B). Conditions for rejection

- i) Consignments which do not meet importation requirements will be rejected by TFDA and the accompanied documents shall be stamped with an official stamp marked "**STOP RELEASE**".
- ii) Drugs rejected for quality reasons will be **CONDEMNED**;
- iii) Drugs rejected because of being unregistered in Tanzania or with neutral labeling, upon application *may* be re-exported to a third country *on special request* and *with special clearance from the Drug Regulatory Authority* of the country where the consignment is being exported to;
- iv) A re-export exercise should be preceded by re-inspection of the rejected consignment to confirm that it is still intact before re-export permit is issued by TFDA;
- v) Re-loading for re-export should be witnessed by Customs officials and Drug Inspector(s) from TFDA;
- vi) Copies of re-export documents stamped at the exit port shall be submitted to TFDA as evidence of completion of re-exportation exercise;
- vii) Destruction of rejected medicines will be done as per the Customs requirements and TFDA will provide technical advice on mode of destruction according to the guidelines of disposal of unfit pharmaceutical products.
- viii) TFDA will issue a Destruction Certificate after completion of the destruction exercise.
- ix) Where the consignment is rejected/detained an inspector will issue a Rejection/Detain Form of pharmaceutical consignment(s) as specified under **Annex V** of these guidelines.

CHAPTER 2

2. EXPORTATION OF PHARMACEUTICAL PRODUCTS AND RAW MATERIALS

2.1 Exporters of pharmaceutical products

Exporters of pharmaceuticals fall under the following categories:

- (i) Registered local pharmaceutical manufacturers
- (ii) Registered wholesalers
- (iii) Clinical trial sponsors and investigators
- (iv) Person authorized by TFDA

2.2 Requirements for exporters

- 2.2.1 No person shall export pharmaceutical products out of the country without having a valid export permit issued by the Authority.
- 2.2.2 All pharmaceutical products to be exported must come from a registered manufacturer or wholesale pharmacy in Tanzania Mainland.
- 2.2.3 All exporters must export pharmaceutical products through the authorized PoE.

2.3 Procedure for exportation of pharmaceutical products

- 2.3.1 Authorized exporter intending to export pharmaceutical products should apply to the Director General, TFDA by filling in application form as prescribed under **Annex VI** of these guidelines.
- 2.3.2 All applications may be submitted to TFDA head quarter offices or TFDA zone offices located in Arusha, Mwanza, Mbeya and Dodoma regions.
- 2.3.3 The application form shall be accompanied by one original proforma invoice.
- 2.3.4 The Proforma invoices shall state for each pharmaceutical product to be exported, the following(s):
 - (i) Profoma invoice number and date,
 - (ii) Name of the exporter,
 - (iii) Country of origin of the product,
 - (iv) Country of destination,
 - (i) Trade or proprietary name,
 - (ii) The International Non Proprietary name (generic name) of the drug and its strength,
 - (iii) In the case of the product containing more than one active ingredient, the name and strength of each shall be stated,
 - (iv) The quantity to be exported for each drug, its unit value, total value and currency,
 - (v) Batch number for each product,
 - (vi) Manufacturing and expiring date,
 - (vii) The quantity and pack size to be exported for each drug,
 - (viii) Mode of shipment (sea, air, road),
 - (ix) Port of exit and
 - (x) Bear stamp and signed by a pharmacist or veterinary surgeon in-charge of the exporting company before submission to TFDA.

- 2.3.5 In a situation where section 1.3.4 (XIV) does not apply, the application form shall be signed by the applicant.
- 2.3.6 Export permit shall not be transferable and shall be issued to cover only one shipment.
- 2.3.7 Application for export permit shall be accompanied by a processing fee as prescribed in TFDA Fees and Charges Regulations in force.
- 2.3.8 After being satisfied by the information submitted, an *Export Permit* will be issued as prescribed under **Annex VI** of these guidelines. The permit will be valid for 6 months from the date of issue.
- 2.3.9 In case of controlled drugs (narcotics, psychotropics and precursors), a proforma invoice will be accompanied by import certificate from a drug regulatory authority of an importing country. The postal address, physical address, email address and/or telephone number of the Drug Regulatory Authority of the importing country have to be clearly indicated.
- 2.3.10 Exporting wholesale pharmacies will be required to provide evidence of source of the exported products.
- 2.3.11 All applications for export will be processed within two working days.
- 2.3.12 Applications for export permit must be submitted 21 days before the shipment of the consignment.
- 2.3.13 An application will be rejected if it does not meet any of the exportation requirements. An applicant will be given a rejection form (**Annex VII**) stating clearly reason(s) thereof.

2.4 Review and Appeal procedure

- 2.4.1 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 of TFDA within a period of 14 days from the date of receipt of the decision.
- 2.4.2 The Authority may review its decision, reject or vary the condition of approval.
- 2.4.3 After reconsideration of the application, if the applicant is not satisfied by the decision of the review, may appeal to the Minister responsible for Health.

ANNEX I

F01/DMC/DMI&E/SOP/002

TANZANIA FOOD AND DRUGS AUTHORITY

Email: info@ tfda.or. tz
Telephone : +255 22 2450512, 2450751
+255 22 2452108
Fax No. +255 22 2450793
Website: www.tfda.or.tz
All letters should be addressed to
the Director General
In reply please quote Our Ref No:



Nelson Mandela Road
EPI – Mabibo External,
P. O. Box 77150,
DAR ES SALAAM,
TANZANIA

APPLICATION FOR IMPORTATION OF PHARMACEUTICAL PRODUCTS AND RAW MATERIALS

To: Director General
Tanzania Food and Drugs Authority
P.O Box 77150, Dar-es-salaam

I/We... of (postal address)...undertaking the business of
Wholesale/Pharmaceutical manufacturing/Other
(Specify)... hereby
apply for importation permit for pharmaceuticals into the United Republic of Tanzania.
Permit Number.....issued on.....Location of
Business.....Name of Pharmacist/Veterinary Surgeon
In-charge of the business.....Registration Number.....
Purpose of importation permit, for:
[] Raw materials and/or packaging materials for production of pharmaceuticals
for human use;
[] Raw materials and/or packaging materials for production of veterinary
medicines;
[] Finished pharmaceutical products for human use;
[] Finished pharmaceutical products for veterinary use;
[] Clinical Trial of a specified product (only one product per application)
[] Personal use
[] Other.....(Specify)
(Tick whichever is applicable)

Attached herewith the Proforma Invoice No... of (date)...

Declaration:

I certify that the information provided in the application form and proforma invoice is true and correct.

Date of application... Signature of Applicant.....
Stamp.....

For official use only:

Received by: Signature.....
Stamp.....

TANZANIA FOOD AND DRUGS AUTHORITY

Email: info@ tfda.or. tz
 Telephone : +255 22 2450512, 2450751
 +255 22 2452108
 Fax No. +255 22 2450793
 Website: www.tfda.or.tz
 All letters should be addressed to
 the Director General
 In reply please quote Our Ref No:



Nelson Mandela Road
 EPI – Mabibo External,
 P. O. Box 77150,
 DAR ES SALAAM,
 TANZANIA

REJECTION FORM

REJECTION OF P/INVOICE NO..... DATE.....
 APPLICATION REF TFDA AP NO..... DATE.....

Reasons for rejection

1. Retention and Registration certificate fees not paid
2. No valid License
3. No valid registration
4. Manufacturer(s) not indicated
5. No P/invoice number shown
6. Name/identity of items is not clear
7. Consignee of goods not registered
8. Active ingredients(s)/INN not declared
9. Product not regulated by the Authority
10. P/invoice is not original/counter signed and stamped by Supplier
11. Certificate of Donation is not attached
12. No signature/Stamp
13. Batch number not shown
14. Product(s) registration number not shown
15. Expiry date(s) not shown in case of donated products
16. Specification(s) not indicated (for Raw materials)
17. Withdrawn from circulation in Tanzanian market/the country of origin/by WHO
18. Others.....(Specify)

Due to the above-mentioned reasons, a new proforma invoice has to be submitted without the following product(s):

1.
2.
3.
4.
5.
6.

.....
 Name of Reviewing Officer

.....
 Signature

.....
 Date

.....
 Name of MMI&E or DMC
 (For Approving Rejection)

.....
 Signature

.....
 Date

.....
 Name of Collecting Person

.....
 Signature

.....
 Date

ANNEX III

P01/DMC/DMI&E/SOP/002

TANZANIA FOOD AND DRUGS AUTHORITY

Email: info@ tfda.or. tz
Telephone : +255 22 2450512, 2450751
+255 22 2452108
Fax No. +255 22 2450793
Website: www.tfda.or.tz
All letters should be addressed to
the Director General
In reply please quote Our Ref No:

Nelson Mandela Road
EPI – Mabibo External,
P. O. Box 77150,
DAR ES SALAAM,
TANZANIA



PERMISSION TO IMPORT REGISTERED PRODUCT (S)
Section 21(1)d of Tanzania Food Drugs and Cosmetics Act 2003
Permit No: TFDA...../D/IPER/.....

PART A:

Name of registered importer.....Postal addressTel No.....
Exporting Country.....Invoice No.....Date.....Time.....
Exporter/Sender..... Postal address
Arrival expected by ship/air/motor vehicle, viaPort of entry
Application for permission to import the following product (s) in accordance with the above mentioned Act
and Regulations made

Table with 6 columns: Sno, Generic name, Brand name, Batch No., Registration number, Permit Quantity, Value of the products

TOTAL:

Fees Receipt No Dated

PART B:

Permission is hereby granted to import the mentioned product(s). The importer has to call in the Port TFDA
Inspector to examine the approved product(s) for fitness for the intended use before being allowed entry into
Tanzania.

Date FOR: Director General and stamp

PART C:

I being TFDA inspector at TFDA port office has examined the above listed
product(s) and have found them fit/unfit for the intended use hence allowed/not allowed entry into
Tanzania.

Date Signature of TFDA port officer and stamp
(The inspector has to return immediately a
completed copy of this permit together
with a copy of a release certificate to the
Director General)

N.B: This permit is for *single consignment* only and shall be valid for *Six Months* from date of approval.

ANNEX IV

F03/DMC/DMI&E/SOP/005

TANZANIA FOOD AND DRUGS AUTHORITY

Email: info@ tfda.or. tz
Telephone : +255 22 2450512, 2450751
 +255 22 2452108
Fax No. +255 22 2450793
Website: www.tfda.or.tz
All letters should be addressed to
the Director General
In reply please quote Our Ref No:



Nelson Mandela Road
EPI – Mabibo External,
P. O. Box 77150,
DAR ES SALAAM,
TANZANIA

SAMPLE COLLECTION FORM

(Made under section 101 (1) of Tanzania Food Drugs and Cosmetics Act 2003)

Name of Institution/Company (under inspection).....

Address.....

Date of inspection/collecting sample.....

Reason for collection (Indicate analysis needed where possible).....

Product name and description/Identification (e.g. colour, dosage form. Etc)
.....

Size of Lot from which sampled.....

Name and address of Manufacturer.....

Batch no.....Manufacturing Date.....Expiring Date.....

Place sampled (Port of entry, Manufacturing plant, Wholesale/Retail Pharmacy, Part II shop, etc.).....

No. of samples taken (tins, packets, etc.).....

Collectors Identification on Seal.....

Name of Representative(s) of the Inspected Establishment/consignment.	Signature	Date
---	-----------	------

(1).....
----------	-------	-------

Name of Drug Inspector(s) (Sampling Officer).	Signature	Date
---	-----------	------

(1).....
----------	-------	-------

(2).....
----------	-------	-------

(3).....
----------	-------	-------

TANZANIA FOOD AND DRUGS AUTHORITY

Email: info@ tfda.or. tz
 Telephone : +255 22 2450512, 2450751
 +255 22 2452108
 Fax No. +255 22 2450793
 Website: www.tfda.or.tz
 All letters should be addressed to
 the Director General
 In reply please quote Our Ref No:



Nelson Mandela Road
 EPI – Mabibo External,
 P. O. Box 77150,
 DAR ES SALAAM,
 TANZANIA

REJECTION/DETENTION OF PHARMACEUTICAL CONSIGNMENT(S)

(Made under section 99 (4) of Food Drugs and Cosmetics Act 2003)

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

- 1. Proforma Invoice is not approved by TFDA
- 2. 2% FOB is not paid to TFDA
- 3. The products (s) is/are not registered by TFDA
- 4. consignee is unauthorized dealer of pharmaceuticals
- 5. Manufacturer of product is not indicated
- 6. Description of the items is not clear
- 7. Manufacturing and/expiring date of products (s) not indicated
- 8. The products (s) shelf life is too short/expired
- 9. Physical quality of the product is poor
- 10. Packaging Insert not included
- 11. Certificate of analysis not present
- 12. Batch No
- 13. Any other.....(Specify)

Comments from the inspector if any.....

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

ANNEX VI

F01/DMC/DMI&E/SOP/00X

TANZANIA FOOD AND DRUGS AUTHORITY

Email: info@ tfda.or. tz
Telephone : +255 22 2450512, 2450751
 +255 22 2452108
Fax No. +255 22 2450793
Website: www.tfda.or.tz
All letters should be addressed to
the Director General
In reply please quote Our Ref No:



Nelson Mandela Road
EPI – Mabibo External,
P. O. Box 77150,
DAR ES SALAAM,
TANZANIA

APPLICATION FOR EXPORTATION OF PHARMACEUTICAL PRODUCTS

To: Director General
 Tanzania Food and Drugs Authority
 P.O Box 77150, Dar-es-salaam

I/We... ..
of (postal address)... ..undertaking the business of
Wholesale/Pharmaceutical manufacturing/Other
(Specify).....
Permit number.....issued on.....
Location of Business.....Name of
Pharmacist/Veterinary surgeon in charge of the
business.....Registration Number.....
Hereby apply for export permit of pharmaceuticals to:
Consignee.....Physical address/Location of
business.....Postal address.....
Country name.....

Purpose of export permit, for:

- Finished pharmaceutical products for human use;
- Finished pharmaceutical products for veterinary use;
- Clinical Trial of a specified product (only one product per application)
- Raw materials and/or packaging materials for production of pharmaceuticals for human use;
- Raw materials and/or packaging materials for production of veterinary medicines;
- Any other (Specify).....

(Tick whichever is applicable)

Attached herewith the Proforma Invoice No.....of (date)... ..

Declaration:

I certify that the information provided in the application form and proforma invoice are true and correct.

Date of application... .. Signature of Applicant.....
Stamp.....

For official use only:

Received by: Signature.....
Stamp.....

ANNEX VII

P01/DMC/DMI&E/SOP/00X

TANZANIA FOOD AND DRUGS AUTHORITY

Email: info@ tfda.or. tz
Telephone : +255 22 2450512, 2450751
+255 22 2452108
Fax No. +255 22 2450793
Website: www.tfda.or.tz
All letters should be addressed to
the Director General
In reply please quote Our Ref No:



Nelson Mandela Road
EPI – Mabibo External,
P. O. Box 77150,
DAR ES SALAAM,
TANZANIA

Permit No.

DATE:

Exporter name

P.O. Box.....

Region.....

RE: PERMIT TO EXPORT PHARMACEUTICALS FROM TANZANIA TO
..... LIMITED, COUNTRY NAME.....

Reference is made to your application letter received on attached with a proforma
invoice number..... dated.....

Subject to compliance with other laws regulating the export trade, permission is hereby
granted to, under section 73(1) of the Tanzania Food, Drugs and
Cosmetics Act, 2003 to export the following product (s) to
COUNTRY NAME.....;

Table with 5 columns: S/no, Item, Unit price, Quantity, Value of the products

TOTAL:

Permission is hereby granted to export the mentioned product(s). This permit is valid from
Date to Date.....

Date

FOR: DIRECTOR GENERAL