GN. No. 312 (contd.)

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THE TANZANIA FOOD, DRUGS AND COSMETICS ACT,

(CAP. 219)

REGULATIONS

(Made under Section 122(1)(e))

THE TANZANIA FOOD, DRUGS AND COSMETICS (REGISTRATION OF PREMISES, IMPORTATION AND EXPORTATION OF PHARMACEUTICAL PRODUCTS AND RAW MATERIALS) REGULATIONS, 2015

ARRANGEMENT OF REGULATIONS

PART I

PRELIMINARY PROVISIONS

Citation

1. These Regulations may be cited as the Tanzania Food, Drugs and Cosmetics (Importation and Exportation of Pharmaceutical Products and Raw materials) Regulations, 2015.

Application and scope

2. These Regulations shall be used for registration for premises for human medicines, importation and exportation of pharmaceutical products and raw materials and shall be applied in Mainland Tanzania.

Interpretation

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3. In these Regulations, unless the context otherwise requires:-

"Act" means the Tanzania Food, Drugs and Cosmetics Act;

"Authority" means the Tanzania Food and Drugs Authority or its acronym "TFDA" established by section 4(1) of the Act;

"business permit" means annual dealer's permit or permit issued to an importer or exporter authorizing him to operate the business of importation or exportation of pharmaceutical products;

"competent Authority" means the Ministry or Department responsible for Health or National Medicines Regulatory Authority in the exporting country;

"controlled drugs" means any narcotic drugs, psychotropic substances or precursors as described in the Act;

"donation certificate" means certificate issued by Competent Authority from the exporting country to certify donation;

"export permit" means a permit issued by the Authority

to an Exporter authorizing him to export pharmaceutical products from Tanzania;

"exporter" means person or institutions authorized under these Regulations to export pharmaceutical products from Tanzania;

"free medical samples" means pharmaceutical products used for promotional purposes;

"free goods" or "free of charge pharmaceutical products" means discounted goods;

"importer" means person or institution authorized under these Regulations to import pharmaceutical products for sale, offer for sale, distribute, supply, donate or use in Tanzania;

"import permit" means a permit issued by the Authority to an Importer authorizing him to import pharmaceutical products into Tanzania;

"inspector" means an inspector appointed, authorized or recognized under the Act;

"investigational pharmaceutical products" means pharmaceutical form of active ingredient or placebo being tested or used as a reference in a clinical trial, including product with a marketing authorization when used or assembled in a way different from the approved form, or when used for approved indication, or when used to gain further information about an approved use;

"minister" means the Minister for the time being responsible for heath;

"market authorization holder" means a person or company in whose name the market authorization or registration of pharmaceutical product has been granted;

"pharmaceutical product" means any pharmaceutical substance or product as defined under the Act;

"prescription" means a lawful written direction by a medical practitioner, dentist or veterinarian for preparation and dispensation of a drug by a

pharmacist;

"port of entry" means entry points of imported or exported pharmaceutical products and raw materials as provided under regulation 10(2) to these Regulations;

"premises" means land, building structures, basements and vessels and in relation to any building includes a part of a building and any cartilage, forecourt, yard or places of storage used in connection with building or part of that building, and in relation to vessel means ship, boat, aircraft and includes a carriage or receptacle of any kind;

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"superintendent" means a pharmacist in charge of import or export and is registered under the Pharmacy Act;

"raw material" means any substance of a defined quality used in the production of pharmaceutical products, but excluding packaging materials;

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

PART II
REGISTRATION OF PREMISES

Premises registration

4. A person shall not store for sale or possess pharmaceutical products except in premises registered under the Act or any other law in force for the time being.

Application for registration of Premises

5. (1) Application for registration of premises regulated under the Act shall be made to the Authority in Form TFDA I specified in the First Schedule of these Regulations and shall be accompanied by a fee as prescribed in the Fees and Charges Regulations in Force.

(2) Without prejudice to the generality of sub regulation (1), the application shall be accompanied by-

(a) a copy of the signed contract between the applicant and Superintendent where applicable; and

(b) a copy of license to practice as a pharmacist for the Superintendent.

Conditions for registration of premises

6. (1) The premises shall be registered if it meets the following conditions:-

(a) located away from sites or activities that emit obnoxious materials like fumes and contaminants, open sewerage, offensive trade or any other place where safety, quality and efficacy of pharmaceutical products cannot be compromised;

(b) designed such that, it shall have no direct link to building with bar, restaurant, medical laboratory, dispensary, clinic or in direct link to residential house where the business is housed;

(c) has a postal address and physical address where the business is to be carried out, clearly indicated in the application form;

(d) durable, safe and made of permanent building materials, roofed with corrugated iron sheets, concrete slabs or tiles and shall have the floor minimally made up of cement or terrazzo or tiles or any other hard washable surfaces so as to protect pharmaceuticals from potential harmful influences;

(e) designed and equipped so as to provide protection against rodents, birds and vermin;

(f) rooms painted with white washable paint with

smooth washable finishing;

(g) surroundings are maintained so as to minimize dust and other contamination to enter the building;

(h) sufficient lighting, ventilation and optimum temperature to enable operations to be carried out;

(i) sufficiently secured to prevent theft and unauthorized entry and

(j) a "NO SMOKING" sign should be conspicuously displayed at the entrance;

(k) has suitable equipment and facilities for proper storage, safety keeping and handling of pharmaceuticals;

(l) has a separate secured cabinet with lock and key for keeping controlled drugs if applicable;

(m) has a minimum total area of at least $40m^2$ with not less than 2.5m internal height and demarcated into rooms for receiving and dispatch, record keeping and storage. The premises must have one main secured entrance; and

(n) the name of the proposed business does not mislead users of pharmaceutical products or violates any provision of the Act or any other written law.

Inspection of premises

7. -(1) Upon receipt of duly filled application form for premises registration, the Authority shall inspect the premises to verify if all the conditions set under these Regulations have been met.

(2) When conducting inspection specified in sub

regulation (1) the Authority shall use the inspection checklist as prescribed in the Guidelines in force for Registration of premises for pharmaceutical importers and exporters.

Issuance of premises registration certificate and business permit

8. (1) The Authority may, if satisfied that the conditions specified in these Regulations are met, register the premises and issue premises registration certificate in Form "TFDA II" specified of the First Schedule.

(2) Notwithstanding sub-regulation (1), a person shall not commence any business in a registered premises unless he has obtained a business permit from the Authority.

(3) A business permit issued under sub-regulation (2) shall be in Form TFDA III specified in the First Schedule to these Regulations and shall expire on 30th June every year.

(4) No person shall transfer or use the certificate or business permit issued under these Regulations, in any other manner other than the purpose it was issued unless he notifies and obtains an approval from the Authority.

Revocation, suspension, cancellation of certificate and permit

9. The Authority may, on reasonable grounds suspend, vary, cancel or revoke premises registration certificate and business permit.

Records and Documentation

10.-(1) Every importer or exporter shall, in respect to his premises, make available the following information:

(a) an appropriate inventory control system;
(b) inspection reports file;
(c) complaints handling book;
(d) unfit medicines register;
(e) controlled drugs register;

(f) recall register;

(g) register for customers detailed with the name of the customer, physical, postal and electronic address, Registration number, name and registration number of the superintendent;

(2) Subject to the conditions provided in sub regulation (1), an importer shall maintain the following documents:

(a) final invoices with corresponding import permits;

(b) copies of delivery notes;

(c) sales invoices.

(3) The documents referred to in sub regulations (2) shall be kept and maintained within the premises for a period of not less than one (1) year after the date of expiry of pharmaceutical product.

Notification for change of name and Superintendent

11. Any change of the name, ownership, superintendent or other changes to the premises registered shall be notified to the Authority.

Restriction to sell imported pharmaceutical products

12. Subject to the provisions of these Regulations, an importer shall sell pharmaceutical products in bulk to wholesalers.

Cessation of business

13.-(1) Where the proprietor intends to close down his business because of any reason(s), he shall officially inform the Authority in advance, so that the disposal of pharmaceutical the provision of products is done under the immediate supervision of the Authority.

(2) Subject to sub-regulation (1), the proprietor shall, within thirty days of the date of cancellation, surrender to the Authority the cancelled certificate or revoked permit, as the case may be.

PART III
IMPORTATION AND EXPORTATION OF PHARMACEUTICAL PRODUCTS AND RAW MATERIAL

Requirements for Importer and Exporter

14.-(1) No person shall import or export pharmaceutical products or raw materials unless he has fulfilled the following conditions:-

(a) has a pharmacist registered by the Pharmacy Council who shall be a Superintendent of the business;

(b) has premises registered by the Authority; and

(c) holds a valid business permit.

(2) Notwithstanding sub regulations (1) importation of raw materials or packaging materials shall be restricted to pharmaceutical manufacturers.

Restriction to import or export pharmaceutical products

1**5.-**(1) No person shall import or export pharmaceutical products or materials unless he is a holder of a valid import or export permit issued by the Authority.

(2) No person shall import any pharmaceutical product unless the product is registered by the Authority.

(3) Notwithstanding sub regulations (1) and (2) the Authority may, upon request by any person or institution and on public interest, approve the importation of unregistered pharmaceutical products.

Applications for Import or Export permits

16.- (1) An application for permit to import pharmaceutical products shall be made to the Authority in Form TFDA IV specified in the First Schedule to these Regulations.

(2) An application for permit to export pharmaceutical products shall be made to the Authority in Form TFDA V specified in the First Schedule of these Regulations as the case may be.

(3) The application under sub regulation (1) and (2) shall be accompanied by the three copies of proforma invoice numbered and dated, duly filled and signed by the superintendent of the business

(4) Subject to provision of sub regulation (3), the proforma invoice shall state, the following-

(a) name and address of the supplier;
(b) name and address of the manufacturer of each product;
(c) trade or proprietary name of each product;
(d) the international non proprietary name (generic name) of the drug and its strength of each product;
(e) in the case of the product containing more than one active ingredients, the name and strength of each shall be stated for each product;
(f) the pharmacopoeia specification of the ingredient such as *BP, USP, JP, PhEur, PhInt* of each product;
(g) the product registration number issued by the authority for each product;
(h) the quantity, pack size, unit value, total value in convertible currency;
(i) batch or lot number where applicable for each product;
(j) manufacturing and expiring date where applicable for each product;
(k) mode of shipment (sea, air, road);
(l) authorized port of entry; and
(m) signature and stamp of the supplier.

Issuance of Import or export permits

17.-(1) The Authority may, after considering the application made to it and being satisfied that the conditions set in these Regulations are met, and upon payment of a fee as prescribed in the Fees and Charges Regulations, issue an import or export permit, as the case may be.

(2) The import permit shall be in the Form TFDA VI prescribed in the First Schedule to these Regulations.

(3) The export permit shall be in the Form TFDA VII prescribed in the First Schedule to these Regulations.

(4) The validity period of import permit shall be six months and for export permit three months from the date of issue.

(5) The import or export permit shall be used for a single consignment and not transferable to any other person.

(6) In the shipping of the consignment takes more than one shipment, three shipments shall be allowed to be covered by one import permit.

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Permit for controlled drugs

18.-(1) Subject to other conditions relating to import permit set in these Regulations, import permit for controlled drugs shall be issued together with the controlled drugs import certificate.

(2) The certificate referred to in sub regulation (1) shall be valid for nine (9) months.

Ports of entry

19.-(1). No person shall, pharmaceutical products through any entry other than the ports of entry specified in the Second Schedule to these Regulations

(2) The ports of entry referred to under sub regulation (1) may be amended, varied or added from time to time.

Conditions for importation of products for personal use

20.-(1). The Authority may, upon application by an individual, and in such amount to be determined by it, authorize the importation of pharmaceutical products for personal use.

(2) Subject to provision of sub regulation (1), application for importation of pharmaceutical products for personal use shall be accompanied by prescription from a registered medical practitioner, dentist or veterinarian and a letter giving reasons for such importation.

(3) Unless the prescription under sub-regulation (2) states otherwise, any *bona fide* tourist or visitor who enters into, or person normally resident who re enters Tanzania, may bring with him such quantity of any drugs as may be required during a period of twenty one days for the medical treatment of himself, or any member, or partner travelling with him.

Conditions for Donated pharmaceutical products

21.-(1) No person shall import donated pharmaceutical products unless he complies with the provisions of these Regulations.

(2) Any person who intends to import donated pharmaceutical products shall make an application by submitting a letter accompanied with the Donation Certificate to the Authority.

(3) The Authority may, upon receipt of the letter and after being satisfied that the conditions set in these Regulations are met, approve importation of donated pharmaceutical products.

Importation of free medical samples

22.-(1) No person shall sell, offer for sale or has in his possession for sale free medical samples.

(2) Subject to other conditions set in these Regulations, importation of free medical samples shall meet the following criteria:

(a) samples shall bear a label printed "**free sample – not for sale**" in bold letters);

(b) samples shall be in a small pack size as compared to commercial pack;

(c) the quantity shall not exceed 300 unit packs per single consignment.

(3) Any application which does not meet the criteria stipulated under sub-regulation (2) shall be charged Free on Board (FOB) accordingly.

Importation of free of charge pharmaceutical product

23.-(1) Subject to other conditions set in these Regulations, application for importation of free of charge pharmaceutical products shall be accompanied by the pro-forma invoice indicating the unit price of each product.

(2) Without prejudice to any other condition set in these Regulations, all free of charge pharmaceutical products shall be charged Free on Board as per Fees and Charge Regulations made under the Act.

Application for importation of investigational medical products

24.- (1) An application for importation of investigational medicinal products shall be made by a clinical trial sponsor or Principal investigator for a study approved to be conducted in Tanzania.

(2) Subject to sub regulation (1), the application shall be accompanied by Clinical Trial Approval Letter issued by the Authority.

Shelf life for imported pharmaceutical products

25. No person shall 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%.

Labeling of imported pharmaceutical products

26. Every importer shall ensure that all imported pharmaceutical products adhere to the following labeling requirements:-

(a) the information printed on labels are indelible, engraved or embossed on a primary and secondary container;

(b) the immediate outer packaging of the pharmaceutical products is clearly labeled in English or Swahili language or both;

(c) the trade or brand name where appropriate is stated;

(d) the international non-proprietary name (generic name) shall be clearly stated;

(e) quantities of active ingredients in the given formulation;

(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 the authority in both outer and inner package of the product(s) where applicable;

(k) package insert literature must be in English or Kiswahili language;

(l) active pharmaceutical ingredient specification such as *(BP, USP, JP, PhEur or PhInt).*

Revocation, cancellation or suspension of import or export permit

27. The Authority may revoke, cancel or suspend any import or export permit or any certificate issued under these Regulations, if it is satisfied that the importer, exporter or consignment contravenes any provision of the Act or these Regulations.

Inspection of imported consignment at Ports of Entry

28. (1) No imported pharmaceutical product shall be removed out of the ports of entry before it is inspected and released by the inspector.

(2) All consignments moved from the ports of entry by direct release administered by Customs Department to other places for storage, such other places shall be deemed to be the ports of entry.

(3) An importer shall avail all necessary documents as may, from time to time, be requested by the inspector.

Sampling

29. (1) When deemed necessary to collect samples or where the inspector suspects that any product in the consignment may contravene any provision of these Regulations or the Act, may take sample for further investigation.

(2) Subject to provision of sub regulation (1) the inspector shall, after collection of samples fill in a sample collection Form TFDA VIII as prescribed in First Schedule.

Rejection or detention of consignment

30.-(1) Where it is in the opinion of the inspector that the consignment be destroyed, he shall recommend the same to the Authority.

(2) Any destruction order made under this regulation shall be done pursuant to the Tanzania Food, Drugs and Cosmetics (Recall, Handling and Disposal of Unfit Products) Regulations, 2014

PART IV
GENERAL PROVISIONS

Review and appeals

31. (1) Any person who is aggrieved by a decision of the Authority he may apply for review of the decision to the Authority.

(2) The Authority may review its own decision.

(3) If a person is dissatisfied by the decision after review, he may appeal to the Minister.

Forms

32. All forms required to be prescribed under these Regulations shall be as specified in the Schedule to these Regulations.

Offence

33. Any person who contravenes or fails to comply with these Regulations or who directly or indirectly aids another person in committing an offence under these Regulations commits an offence under the Act.

Penalty

34. Any person found guilty of an offence under these Regulations shall be liable to the penalty prescribed by the Act.

(Made under Regulation 32)

FIRST SCHEDULE

FORMS

TFDA I

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH AND SOCIAL WELFARE

APPLICATION FORM FOR REGISTRATION OF PREMISES AND BUSINESS PERMIT

(Made under Regulation 5(1))

Director General
Tanzania Food and Drugs Authority
P.O Box 77150
Dar es Salaam

SECTION A: APPLICANT INFORMATION

I / We hereby apply for registration of my/our existing/ new premises and business permit in accordance with the Tanzania Food, Drugs and Cosmetics Act, Cap 219

1. Name of applicant……
2. Postal address……Tel, No…….Fax……..Email……..
3. In case of
(a) *Corporate body; name of Directors.....
(b) *Partnership; name of Partners.....
(c) Joint venture; name of Consortium.....
4. Situated at/lying between Plot /Vessel/ Truck No ……
……Street/Village/Ward……District/Municipality/City
5. Premises to be registered for the business of
……

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6. The importation business will be under the Superintendent, Mr /Ms /Mrs. /Dr. /Prof (Full name)……..……who is a Pharmacist and his/her registration number is …….of ……(Year). (Please attach a copy of registration certificate and contract agreement)

7. The proposed name of the premises is ……..

SECTION B: DECLARATION BY APPLICANT

8. I/we.....have not been convicted for any offence relating to any provision of the Tanzania Food, Drugs and Cosmetics Act, Cap 219 and Regulations made there under or any other written law related to the business being applied for within 12 months immediately preceding this application neither disqualified nor suspended.

N.B. False declaration constitutes an offence.

Date……..
Signed…….
Applicant
* Attach Certificate of Incorporation

TFDA II

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH AND SOCIAL WELFARE

PREMISES REGISTRATION CERTIFICATE

[Made under Regulation 8(1)]

This is to certify that the premises owned by M/S ……. of (Postal Address)……which is located on Plot No.....Block...../Vessel/Truck No…….. Situated/lying between …… Street, in ……..Village/Township/Municipality/City, has been registered as ……..…… ……with Registration Number…….. of 20…….

1. Subject to the following conditions:- The premises and the manner in which the business is to be conducted must conform to requirements of the Tanzania Food, Drugs and Cosmetics Act, Cap 219 or any other written law related to the premises registration at all times failing of which this certificate shall be suspended or revoked
2. Any change in the ownership, name and location of the registered premises shall be approved by the Authority.
3. This certificate is not transferable to other premises or to any other person
4. This certificate shall be displayed conspicuously in the registered premises.
5. The certificate shall only be used to operate business related to products approved by TFDA.

…… ……

Date **Signature of Director General**

Seal

*: Delete whichever is not applicable

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TFDA III

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH AND SOCIAL WELFARE

[Made under Regulation 8 (3)]

BUSINESS PERMIT

Permit No……

Permit is hereby granted to M/S ……. ……of P.O.Box……to Import and/or Export ……. at the premises situated/lying between …… ……Street, Plot/Block/Vessel/Truck No…….…..in ……Village/Township/Municipality/City with Registration No…… of 20…….

This Permit shall have and continue to have effect from and including the day when it is issued until it ceases to have effect on 30th June……..

Issued on…….. Fees paid Tshs……
Receipt No…… Dated ……..

…… ……
Date **Signature of Director General**
seal

CONDITIONS

1. This Permit does not authorize the holder to operate business in unregistered premises or during the period of suspension, revocation or cancellation of registration of the premises in respect of which it was issued.
2. This Permit is not transferable without a written approval of the Authority.
3. A sign board should be conspicuously displayed and the identification logo displayed at the main entrance,

N.B: Delete whichever is not applicable.

TFDA IV

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH AND SOCIAL WELFARE

APPLICATION FOR IMPORTATION OF PHARMACEUTICAL PRODUCTS

[Made under Regulation 16(1)]

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

I/We... ... ... ……...
of (postal address)... ... ...undertaking the business of
Importation, hereby apply for permit to import pharmaceutical products into Tanzania through ………………………………………………. port of entry.

Premises Registration Number …………………………. Of ………………………………………
Name of Superintendent Pharmacist ……………………….Registration Number…………………

Purpose of import permit: (tick where applicable)

☐ Importation of raw materials and/or packaging materials for production of pharmaceuticals for human use;
☐ Importation of raw materials and/or packaging materials for production of veterinary medicines;
☐ Importation of Finished pharmaceutical products for human use;
☐ Importation of Finished pharmaceutical products for veterinary use;
☐ Importation of a specified product for Clinical Trial (one product per application)
☐ Importation of Pharmaceutical product for Personal use
☐ Other………………………………… (Specify)

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... ... ...

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Signature of Superintendent Pharmacist.....

Stamp……....

For official use only:

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

Stamp.....

TFDA V

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH AND SOCIAL WELFARE

APPLICATION FORM FOR EXPORTATION OF PHARMACEUTICAL PRODUCTS

[Made under Regulation 16(2)]

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

I/We... ... ... ……..
of (postal address)... ... ...undertaking the business of Exportation, hereby apply for permit to export pharmaceutical products from Tanzania through ………………………………………………. port of entry.

Premises Registration Number …………………. Of …………………………………
Name of Superintendent Pharmacist …………………………………………………….
Registration Number…………………

Name of Consignee…………………………………………………………… Physical address/Location of business……………………………………………………..Postal address…………………….. Country name……………………………………………

Purpose of export permit: (tick where applicable);

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

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

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

Date of application... ... ...
Signature of Superintendent Pharmacist.....
Stamp……...

For official use only:
Received by: ..... . Signature.....
Stamp.....

TFDA VI

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH AND SOCIAL WELFARE

A FORM FOR PERMIT TO IMPORT PHARMACEUTICAL PRODUCTS

(Made under Regulation 17(2))

Permit No: TFDA.....

PART A:

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

Exporting Country**.....**Invoice No**.....**Date**.....**Time**.....**

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

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

S/N				Product	Permit Quantity	Value of the products
	Generic name	Brand name	Batch No.	Registration number		

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**

N.B: 1. This permit is for *single consignment* only and shall be valid for *Six Months* from date of approval.

2. The inspector has to return immediately a completed copy of this permit together with a copy of a release certificate to TFDA.

TFDA VII

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH AND SOCIAL WELFARE

A FORM FOR PERMIT TO EXPORT PHARMACEUTICAL PRODUCTS
(Made under Regulation 17(3))

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, Cap 219 to export the following product (s) to .....…….. COUNTRY NAME……;

S/N	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…….. ….....

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_____ _____

Date **FOR: DIRECTOR GENERAL**

N.B: 1. This permit is for *single consignment* only and shall be valid for *three months* from date of approval.

2. The inspector has to return immediately a completed copy of this permit together with a copy of a release certificate to TFDA.

TFDA VIII

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH AND SOCIAL WELFARE

SAMPLE COLLECTION FORM

[*Made under Regulation 29(2)]*

1. Sample code: .....
   (Region/product/sequence number/sampling date ddmmyy)
2. Name of Premises where sample was taken:.....
3. Physical Address..... .....Postal address.....
   Telephone No..... .....Fax No.....
   Email address..... (if applicable)
4. Product name of the sample: .....
5. Name of active pharmaceutical ingredient(s) (INN) with strength:.....
6. Dosage form (tablet, oral powder, etc): .....
7. Package size & type: .....
8. Batch/lot number:.....Date of manufacture: .....Expiry date: .....
9. Name and physical address of the manufacturer:
   .....
10. Number of units collected.....
11. Is the product registered in Tanzania? Yes/No. If Yes, indicate the registration number:.....
12. Comment on storage condition of product at the premises:.....
    .....
    .....
13. Name and signature of the Representative of the premise where sample was collected:
    Name.....Signature.....Date..
14. Name of Drug Inspector (s)/Sampling officer

S.No	Name	Organization	Signature	Date

Note: Samples collected must remain in their original containers

SECOND SCHEDULE

(Made under Regulation 19(1))

AUTHORIZED PORTS OF ENTRY

Pharmaceutical products imported and/ or exported into and/or from Tanzania as the case may be shall be allowed to enter through the following official ports of entry

1. Dar-es-salaam International Airport,
2. Dar es salaam Sea Port,
3. Kilimanjaro International Airport,
4. Horohoro
5. Holili,
6. Namanga,
7. Sirari,
8. Mwanza Lake Port,
9. Mwanza Airport,
10. Tanga Sea Port,
11. Tunduma
12. Mtukula
13. Rusumo
14. Kabanga
15. Kasumulo

The Authority reserves the final decision in case of importation or exportation of pharmaceutical products through other ports of entry than the above ports of entry.

Dar es Salaam
10th May, 2015

SEIF SELEMAN RASHID
Minister for Health and Social Welfare