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TANZANIA FOOD AND DRUGS AUTHORITY



***GUIDELINES FOR REGISTRATION OF PREMISES AND LICENSING OF
PHARMACEUTICAL BUSINESS***

Second Edition

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ABBREVIATIONS

1. CFDC - Council Food and Drugs Committee
2. DDI - District Drug Inspector
3. DMO - District Medical Officer
4. DVO - District Veterinary Officer
5. PCT - Pharmacy Council of Tanzania
6. RDI - Regional Drug Inspector
7. RMO - Regional Medical Officer
8. TFDA - Tanzania Food and Drugs Authority
9. TFDC - Tanzania Food, Drugs and Cosmetics, Act
10. TMC - Tanzania Medical Council
11. VCT - Veterinary Council of Tanzania

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FOREWORD

The Tanzania Food and Drugs Authority 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.

The Act empowers TFDA to register premises and issue permits for storing and selling of medicinal products. The registration of premises is done to ensure that they meet prescribed requirements for storage and distribution of pharmaceutical business. Furthermore, the Act provides for regulation of promotion activities related to drugs such that those who are dealing in drug promotion activities are required to be registered by TFDA.

In order to enhance enforcement of the Act, TFDA has developed these guidelines entitled 'Guidelines for Registration of Premises and Licensing of Pharmaceutical Business'. The guidelines provide guidance to dealers in pharmaceuticals, new applicants and the public on the procedure for submitting applications, requirements for registration of premises and licensing of pharmaceutical business as well as registration of medical representatives involved with medicines promotion.

It is therefore anticipated that pharmaceutical dealers and other stakeholders will strive to meet the requirements stipulated in the guidelines so as to ultimately ensure that medicinal products are stored, distributed and sold from well constructed and maintained premises to ensure their quality and safety in order to promote and improve public health.

It is anticipated that the guidelines will be revised regularly in response to experiences gathered from their utilization. We therefore encourage all users and the public to give comments and views on the guidelines at any time.

M. Ndomondo- Sigonda
Director General
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INTRODUCTION

Registration of premises for dealing in pharmaceutical businesses is a prerequisite requirement prior to commencing of such businesses. This requirement is stipulated under section 18 of the Tanzania Food, Drugs and Cosmetics Act 2003. The legislation prohibits the use of any premises for the manufacture, sale, sell, supply or storage of pharmaceuticals unless the premises has been registered by the Tanzania Food and Drugs Authority (TFDA) for that purpose. Furthermore to this, section 20 of the same Act requires all dealers in such business to apply to the Authority for licenses and obtain such license before starting operation.

Registration of premises and licensing of pharmaceutical businesses shall not be considered as the sole means of controlling operations of these premises. However, there are other valuable means of aid in enforcing relevant legislation, such as adherence to good hygienic and pharmacy practices that ensure day-to-day operations of these premises are in line with the laws and regulations. Basing on these grounds, the Authority is empowered to suspend or revoke the registration certificate and license of any premises found to operate contrary to the law.

The revised guidelines have been improved by introducing additional requirements for registration of premises such as minimum distance between retail pharmacies. This requirement intends to enhance a fairly distribution of the outlets as well as accessibility of drugs in different areas. The guidelines have also stipulated sizes for retail as well as wholesale pharmacies. The requirement intends to set uniformity of size for wholesale and retail pharmacies

The guidelines consist of two main parts: the main guidelines and six annexes.

The main guidelines give a procedure for application for registration of premises and pharmaceutical business permit. It gives also a guidance on location, premises design and layout, required personnel, storage facilities, sanitation and hygiene, stock control and handling, records and documentation, recalls, reject and withdrawal, cessation of business, validity of premises registration and pharmaceutical business permit, payment of fees, language, notification for change of any or alteration of registered premises, refusal or revocation of registration certificate and permit, appeals and required reference materials.

The annexes include format for application forms, registration certificate of premises, business permit, medical representative permit, inspection checklists and particulars/contents for records books.

Dealers should note that, the requirements stipulated in these guidelines are deemed to be minimum. In view to that all dealers are encouraged to adhere to these requirements.

DEFINITIONS OF TERMS

1. **Equipment-** Means machines, instrument, apparatus, utensil or appliance, other than a single use item, used or intended to be used in or in connection with pharmaceutical handling and include any equipment used to/intended to be used to clean pharmaceutical premises facility.
2. **Business-** Includes professional practice and any activity carried on by person or a body of persons in relation to products regulated under TFDC Act 2003.
3. **Premises-** Includes 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.
4. **Sell-** Means sell by wholesale or retail and include import, offer, advertise, keep, expose display, transmit, consign, convey or deliver for sale or authorise, direct or allow a sale or prepare or posses for the purpose of sale and barter or exchange supply or dispose of to any person whether for a consideration or otherwise.
5. **Products regulated Under the TFDC Act, 2003-** Means Food, Drugs, Cosmetics, Herbal drugs and Medical devices.
6. **Authority-** Means the Tanzania Food and Drugs Authority or the acronyms TFDA established under section 4 of the TFDC Act 2003.
7. **Director General-** Means the Chief Executive of the Tanzania Food and Drugs Authority appointed under section 8 (1) of the TFDC Act, 2003.
8. **Dispense-** Means supply of a drug, drug product or poison on and in accordance with a prescription lawfully given by a medical practitioners, dentists or veterinary surgeon.
9. **Controlled drugs-** Means any narcotic drug, psychotropic substance or precursor chemical as provided under section 77 of the Tanzania Food, Drugs and Cosmetics Act, 2003.
10. **Drug, medicine or pharmaceutical product-** Means any substance or mixture of substances manufactured, sold or presented for use in;
 - (i) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical or mental state, or the symptoms thereof, in man or animal; or
 - (ii) restoring, correcting or beneficial modification of organic or mental functions in man or animal or;
 - (iii) disinfection in premises in which drugs are manufactured, prepared or kept, hospitals, equipment and farm houses;
 - (iv) Articles intended for use as a component of any articles specified

in clause (a), (b) or (c); but does not include medical devices or their components, parts or accessories.

11. **Inspector**- Means an Inspector appointed, authorized or recognized under section 105 of the TFDC Act, 2003.
12. **Pharmacy**- Includes a registered pharmacy department in a hospital, clinic or health centre or a community pharmacy.
13. **Retail Pharmacy business**- Means a business, which consists of or includes the retail sale of drug products but does not include professional practice carried on by Medical practitioner, dentist or veterinary surgeon.
14. **Superintendent**- Means any person who is a manager and controls the business of a pharmacist.
15. **Wholesale pharmacy business**- Means a business which consists of or includes the wholesale of drug products but does not include professional practice carried out on by medical practitioner, dentist or veterinary surgeon.

**1. PROCEDURES FOR APPLICATION FOR REGISTRATION OF PREMISES
AND PERMITS PRIOR TO OPERATE THE BUSINESS OF
PHARMACEUTICALS**

****Applicants shall read carefully and understand these guidelines before engaging in construction of the intended premises.***

- 1.1. Applicants are required to get a copy of these Guidelines and read carefully before engaging in construction of the intended premises.
- 1.2. Application for premises registration and permits to operate the business of pharmaceuticals or renewal of permits shall be made in a prescribed application forms to the Director General TFDA through TFDA offices or respective RMO/DMO. The application shall be accompanied with a fee as prescribed under TFDA Fees and Charges Regulations, 2005 and paid as per section 13 of these guidelines. The format of the application form is provided as **Annex I**.
- 1.3. The Application forms shall be obtained from the secretary to CFDC, DMOs or RMOs offices of the respective Districts or Regions respectively, TFDA zone and headquarter offices or through the TFDA Website www.tfda.or.tz
- 1.4. Applicant shall be required to fill accurately all the required information in the application form.
- 1.5. Applicants shall furnish their applications to the respective district drug inspector before any construction/renovations are made into the premises.
- 1.6. Applicant shall be required to submit a proof of citizen from the relevant authorities and in case of a company; a least one Tanzanian share holder must be present.
- 1.7. If the applicant is not a superintendent, he/she shall be required to secure the services of a pharmacist as in-charge of the business. In case of a wholesale veterinary medicines business, the in-charge can be either a pharmacist or veterinary surgeon.
- 1.8. The applicant shall be made to sign a contract agreement with the superintendent/in-charge of the business and submit the true copy of the original contract to TFDA for record purposes and attach a copy of registration certificate of the superintendent as issued by the respective councils or professional boards.
- 1.9. Applications may be attached with a sketch design of the proposed premises whereby, the Authority through the authorized drug inspector shall go through it to authenticate if it suits the purpose of that proposed business.

- 1.10. The proposed business name shall be subject to further review by the Authority before the applicant forwards it to the registrar of business names.
- 1.11. The Authority may approve or reject the submitted sketch design and the applicant will be informed accordingly.
- 1.12. The applicant shall continue with process of construction/renovation of the premises and registration of business names and upon completion shall inform the authority for inspection.
- 1.13. The District drug inspector or any other inspector shall make sure that the premises applied for registration is inspected to verify if all the requirements have been met.
- 1.14. In the areas where TFDA office is located such as TFDA head office or zone offices, the inspection shall be jointly conducted by the TFDA inspector.
- 1.15. The inspectors shall when conducting the inspection of that premises use the inspection checklist for new pharmaceutical premises and give their observations and recommendation on the suitability of the premises in the application form. A format of that checklist is provided as **Annex II**.
- 1.16. The inspectors shall make sure that the necessary applicant information are accurately provided as requested in the application form and all information required in the inspection checklist are properly filled.
- 1.17. Inspectors shall also make sure that the full name, registration number and status of the immediate premises superintendent is provided, including his letter of commitment to accept the supervision of the said premises.
- 1.18. Upon receipt of duly filled in TFDA application forms, premises inspection report and all other necessary documents from the drug inspectors the Manager of Medicines Inspection & Enforcement shall scrutinise all the documents and if satisfied that all the requirements have been met, shall compile and give its recommendations to TFDA Internal Technical Committee of Inspection and Licensing of Pharmaceutical and Cosmetics Businesses for approval.
- 1.19. In case if Premises registration or licensing requirements have not been met, the applicant will be informed accordingly to address the shortfalls before considerations.
- 1.20. The Directorate through the TFDA Internal Technical Committee of Inspection and Licensing of Pharmaceutical and Cosmetics Businesses may approve, withhold or reject any application by providing reason(s) for its decision of withhold or rejection.

- 1.21. All applicants, whose applications have been approved, withhold or rejected as the case may be, shall **within one week** from the day, which the decision was made, send with an official letter informing them on the status of their application.
- 1.22. Applicants, whose applications have been withheld for any reasons shall be required to carry out corrective measures before they are legible for reconsideration.
- 1.23. Before starting the business, approved applicants will be required to procure pharmacy identification logo from TFDA offices and other reference materials related to this type of business.
- 1.24. The Authority shall then issue the Premises Registration Certificate and the respective retail, wholesale, retail and wholesale or warehouse permits which allow the applicant to start carrying out the business of a pharmacy.
- 1.25. Every permit for the business of pharmacy shall expire on the 30th June every year. Therefore all dealers of pharmaceutical business shall be required to fill and furnish to TFDA offices their applications for renewal of permits three (3) months before 30th June.
- 1.26. The renewal shall be done by only filling in the application form for permit and pay the respective annual permit fee prescribed under TFDA Fees and Charges Regulations, 2005.
- 1.27. Dealers who shall delay to renew their permits beyond 31st July every year shall be required to pay the Authority the prescribed annual permit fee together with 25% penalty. Contrary to that, registration certificate may be revoked and the premises closed down.

2. LOCATION

- 2.1. The premises shall be located away from sites or activities that emit obnoxious materials like fumes and contaminants, open sewerage, offensive trade etc.
- 2.2. Premises located within or near petrol station shall be furnished in such a way that the activities including fuel fumes does not affect in any way the quality of medicines and dispensation process in the pharmacy. The premises shall be required to address among other issues, the fire prevention facilities.
- 2.3. Premises located within shopping centres, e.g. shopping malls, supermarkets etc, shall be confined and restricted from other activities conducted thereat.
- 2.4. The premises shall be designed such that, it shall have no direct link to building with bar, restaurant, medical laboratories, dispensary, clinics or in direct link to residential houses where the business is housed.

- 2.5. The premises should have a postal address and physical address of the premises to include plot and house number, street/hamlet, district and region where the business is to be carried out, clearly indicated in the application form for easy communication and reach during supervision and inspection.
- 2.6. The premises should have a sign board conspicuously displayed and the pharmacy identification logo displayed at the main entrance.
- 2.7. Registration of premises shall be approved if the new premises is at least 300 metres away from the existing pharmacy. However, the Authority shall have power to review this requirement from time to time basing on the service need by the community and population increase.
- 2.8. Veterinary pharmaceutical products may be sold in livestock markets where there are no veterinary pharmaceutical outlets nearby and the following shall be the requirements;
 - 2.8.1 Dealers must be a retail pharmaceutical dealer with a registered premises.
 - 2.8.2 Must have a permit for transportation of veterinary pharmaceuticals and selling by using a mobile van. Selling shall be restricted at the car only to maintain the quality of drugs.

3. PREMISES DESIGN

- 3.1. The premises shall be durable, safe and made of permanent building materials so as to protect pharmaceuticals from potential harmful influences.
- 3.2. The premises shall be roofed with corrugated iron sheets, concrete slabs or tiles and shall have the floor minimally made up of cement, terrazzo, tiles or any other hard washable surfaces.
- 3.3. The premises shall be designed and equipped so as to provide protection against rodents, birds, vermin etc
- 3.4. The rooms shall be painted with white washable paint with smooth washable finishing.
- 3.5. The surrounding should be maintained so as to minimise dust, soil and other contamination to enter the building.
- 3.6. Sufficient lighting and ventilation shall be provided to enable all operation to be carried out.
- 3.7. Premises should be sufficiently secured to prevent theft and unauthorised entry and a **“NO SMOKING”** sign should be conspicuously displayed at the entrance.
- 3.8. The premises shall be provided with suitable equipment and facilities for

proper storage, safety keeping and handling of pharmaceuticals.

- 3.9. Van for carriage or transportation and selling of the pharmaceuticals shall be of light colour and easily cleaned. It shall be dust proof, insulated, ventilated, water tight, covered to prevent direct sunlight and provided with special facilities to maintain cold chain.
- 3.10. In retail outlets where compounding of extemporaneous preparations is taking place there shall be availability of simple dispensing equipment like balances, mortar and pestle, measuring cylinder and a sink in the dispensing area.
- 3.11. In Premises providing both human and veterinary drugs, separate displaying shelves and storage cabinets shall be provided for each category.
- 3.12. Premises dealing in pharmaceutical products shall not stock in the same registered premises chemicals or pesticides used exclusively for plant protections.
- 3.13. Premises shall have separate secured cabinets with lock and key for keeping controlled drugs.
- 3.14. Approval of storeroom located within the pharmacy or warehouse at mezzanine or underground shall be subject to adherence to other premises requirements including provision of sufficient light, air conditioning facilities etc.

4. PREMISES LAYOUT

4.1. RETAIL PREMISES

- 4.1.1. Retail Pharmacy shall have a minimum of two rooms with clear demarcation and linked to each other for displaying and dispensing & store room. The premises must have one main secured entrance.
- 4.1.2. The minimum total size/ area of the premises shall at least measure 20m². The rooms should have not less than 2.5m internal height.
- 4.1.3. The rooms should be equipped as indicated in the inspection checklist with adequate shelves or pallets as the case may be for proper display and storage of medicines respectively.

4.2. WHOLESALE PREMISES

- 4.2.1. Wholesale pharmacy shall have not less than three rooms with clear demarcation and linked to each other for display, receiving and dispatch, record keeping and storage. The premises must have one main secured entrance.

- 4.2.2. The premises shall have a minimum total size/ area of at least 40m². The rooms should have not less than 2.5m internal height.
- 4.2.3. The rooms should be equipped as indicated in the inspection checklist with adequate shelves and pallets for proper display and storage of medicines respectively.

4.3. RETAIL AND WHOLESALE PREMISES

- 4.3.1 Premises for both retail and wholesale business shall have at least three rooms namely; display, receiving and dispatch room; sales, record keeping and dispensing room; and the storage room.
- 4.3.2 The minimum total size/ area of the premises shall at least measure 40m². The rooms should have not less than 2.5 m internal height.
- 4.3.3 The rooms should be equipped as indicated in the inspection checklist with adequate shelves and pallets for proper display and storage of medicines respectively.
- 4.3.4 A clear demarcation of wholesale receiving/dispatch area from the retail part shall be provided to allow orderly receipt/dispatch of pharmaceuticals in bulk.

4.4. WAREHOUSE PREMISES

- 4.4.1 Warehouses shall be designed and constructed to ensure good storage conditions, sufficient lighting and ventilation.
- 4.4.2 Warehouses shall have sufficient capacity to allow storage of various categories of pharmaceutical products.
- 4.4.3 The floor shall be durable to withstand heavy traffic and loads; the premises shall be provided with well-fitted shelves or pallets.
- 4.4.4 The premises shall be equipped with temperature and humidity control facilities/monitors and fire extinguishers.
- 4.4.5 A residential home shall not be used as a warehouse.
- 4.4.6 Warehouse shall only be used for storage purposes and no sells shall be allowed.

5. PERSONNEL

- 5.1. Permit to sale, supply, stock, dispense and compound any pharmaceutical product on retail or wholesale shall not be issued or renewed unless the person applying for holding such permit is or has a superintendent who is a registered pharmacist in direct control of distribution of drugs.

- 5.2. The superintendent shall not act in a similar capacity for any other body corporate.
- 5.3. In case of a wholesale permit to sell veterinary drugs, shall only be issued or renewed if the person applying for holding such permit is or has a registered pharmacist or registered veterinary surgeon in direct control of veterinary drugs.
- 5.4. The pharmacist or veterinary surgeon as the case may be, must be respectively registered by the Pharmacy Council of Tanzania (PCT) or Veterinary Council of Tanzania, (VCT) and must reside in the locality where the business is carried out and shall not be an employee of any other organisation or institution.
- 5.5. In addition to clause 5.4 the veterinary surgeon, may be required to attend a special training course in handling of pharmaceuticals as approved by the Authority.
- 5.6. Pharmacy shall be supervised by a superintendent who may be assisted by another pharmacist, pharmaceutical technician or pharmaceutical assistant recognized by the PCT.
- 5.7. Personnel that shall be allowed to sell veterinary pharmaceutical products in livestock markets must be a veterinary surgeon or a diploma holder in Animal Health.
- 5.8. The owner shall ensure that unqualified personnel who do not possess the prerequisite knowledge do not have access to handling or dispensation of pharmaceuticals.
- 5.9. If the owner is not a superintendent, he shall be made to sign a contract agreement with superintendent of which among other things shall address the terms of terminations.
- 5.10. Neither superintendent nor owner shall terminate such contract agreement without a prior notice to the Authority and if the Authority is satisfied that the business is not supervised by any superintendent, that business may be closed.
- 5.11. Every personnel working in the pharmacy shall observe and maintain the following;
 - (i) high standard of personal hygiene;
 - (ii) wear a clean white coat;
 - (iii) not to work under the influence of alcohol or illicit drugs;
 - (iv) conduct himself/ herself under good and orderly behaviour;
 - (v) wear identity badge;
- 5.12. The superintendent shall be answerable for conducts of personnel working under his instructions.

MEDICAL REPRESENTATIVES

- 5.13. No person shall promote pharmaceutical products except in accordance with the Code of Conduct for Promotion as provided in the regulations and as per Part VII of the Tanzania Food, Drugs and Cosmetics Act, 2003.
- 5.14. Any person who intends to engage in drug promotion must have minimum basic diploma knowledge in pharmaceutical sciences, medical sciences, dental sciences, or veterinary sciences from the recognised institution or any other approved knowledge by TFDA in consultation with other relevant authorities such as VCT, TMC, and PCT.
- 5.15. Any person who intends to engage in drug promotion shall apply in prescribed form to the Director General, TFDA.
- 5.16. Applications shall be accompanied by relevant fees as prescribed under the Fees and Charges Regulations, 2005.
- 5.17. Applicants shall ensure that all related profession credentials are attached to the application form.

6. STORAGE FACILITIES

- 6.1. Storage facilities shall protect products from deterioration or infestation by vermin and pests. Specified storage conditions shall be monitored and maintained accordingly.
- 6.2. Controlled storage environment e.g. air conditioning, refrigeration for cold chain products shall be monitored using suitable temperature recording devices and records reviewed and filed.
- 6.3. There should be provision for lockable shelves for keeping controlled substances.
- 6.4. A confined adequate space shall be provided within the premises for storage of returned, recalled, expired, quarantined and substandard or counterfeit pharmaceuticals.
- 6.5. All pharmaceuticals shall be stored off the floor in well – fitted shelves or pallets.

7. SANITATION AND HYGIENE

- 7.1. To maintain hygienic working conditions, premises shall have good supply of portable water and proper sink for hand washing.
- 7.2. The premises shall have a toilet or nearby accessible toilet.

- 7.3. Personnel shall not be allowed to serve the pharmacy if for the time being suffers from any disease in a communicable form, having boils sores, infected wounds where there is reasonable possibility of medicines becoming contaminated.

8. STOCK CONTROL AND HANDLING

- 8.1. Any undertaking relating to receiving, keeping, selling, dispensing and compounding of pharmaceutical products shall be subject to control by the Authority. All pharmaceuticals shall be properly labelled and stored in suitable and secured places.
- 8.2. Theft and losses of pharmaceuticals shall be reported to police and TFDA immediately.
- 8.3. Repackaging and re-labelling of pharmaceuticals are prohibited.
- 8.4. Storage, supply, distribution and recording of controlled drugs and antiretroviral drugs must be in accordance with the respective guidelines.

9. RECORDS AND DOCUMENTATION

- 9.1. Any person who owns a pharmaceutical business shall make available the following recording books of which superintendent shall cause to record related information whose particulars in each of recording books.
- (a) ledger book or an appropriate inventory control system
 - (b) sales book
 - (c) inspection reports file complaints handling book
 - (d) Expired drugs Register
 - (e) controlled drugs register

In addition to above records, a retail pharmacy shall maintain a dispensing book for enabling traceability of any drug dispensed.

- 9.2. A wholesale pharmacy in addition to the requirements given in clause 9.1 above, shall maintain the following records;
- (a) Final invoices with corresponding certificate of importation
 - (b) recall book
 - (c) Copies of delivery notes.
- 9.3. The dispensing register and the retained prescription shall be kept and maintained within the premises for not less than two years from the date such prescriptions were last made to it.

10. RECALLS AND WITHDRAWAL

- 10.1. There shall be a prompt and effective system of recall from the market for products known or suspected to be defective. A progress report on the recall level shall be submitted to TFDA weekly following the directive from the Authority and the recall shall be completed within sixty (60) days of the directive.
- 10.2. In case of recall of product initiated by the dealer himself, the Authority shall be notified on the reason of recall.
- 10.3. Recall operations shall be capable of being initiated promptly at least down to the level of hospital, dispensary /clinic and pharmacies.
- 10.4. The distribution records shall be readily available to the person(s) responsible for recalls and they shall contain sufficient information related to the product, e.g. Name of product in brand and generic, Manufacturer, Dates of Manufacture and Expire, and Batch Number.
- 10.5. The disposal of recalled, rejected or withdrawn products from the market shall be effected within one month after completion of exercise.
- 10.6. Disposal exercise shall be carried out under supervision of TFDA inspectors and representatives from other Government Institutions as prescribed in the Disposal Guidelines.

11. CESSATION OF BUSINESS

- 11.1. The Authority may at any time suspend a permit as it may determine, or revoke, or vary any provisions of such permit. Such suspension and/ or revocation shall lead the Authority to revoke the premises registration certificate.
- 11.2. Any permit that has been suspended and/ or revoked in accordance with the provision of the Tanzania Food, Drugs and Cosmetics Act, 2003 may not be renewed except with the consent of the Authority if satisfied with the reasons given by the prior permit holder.
- 11.3. The Authority among other reasons may issue or declare a business closed down and deleted from the register, if for any reason such premises will be found operating contrary to the prescribed requirements and standards stipulated in the Act.
- 11.4. Subject to conditions set out in work contract agreement between the proprietor and the superintendent, the operation of the business shall be closed down and deleted from the register if the notice given by the superintendent expires without the proprietor being able to secure the supervision of another superintendent.

- 11.5. Where the superintendent has given the proprietor a notice, the superintendent shall continue to supervise the premises and the proprietor shall during those days continue to pay the superintendent monthly salaries until the end of the notice or any changes within the notice, such notice given either by the proprietor or the superintendent must be furnished to the Authority.
- 11.6. If the proprietor wishes to close down his business because of any reason(s), he shall officially inform the Authority in advance, so that the disposal of pharmaceutical products is done under the immediate supervision of the superintendent.
- 11.7. A business that has been issued with a closure order shall surrender the premises registration certificate and valid permit to the district or regional drug inspector or TFDA depending on the location of the premises.
- 11.8. The district, regional or TFDA inspectors as the one may be shall have the responsibility of making follow up to ensure that no registration certificate or permit remain in unauthorised hands.
- 11.9. Businesses that have been issued with closure order shall be deleted from register immediately and in case they would wish to re- open their premises, they shall be required to apply as new applicants.
- 11.10. If it happens the superintendent dies, the Authority shall give the proprietor a 90 days closure notice to look for another registered superintendent or else dispose of his stock to lawfully registered dealers. During that time the business may be under the immediate supervision of a diploma holder in the related profession.
- 11.11. Any person or representative of any deceased person who immediately before his death was lawfully in possession of any permit to deal with pharmaceuticals, or any appointed liquidator, receiver or other person dealing with the property of any person who has ceased to be entitled to possess any permit to deal with pharmaceuticals, may with written permission be allowed by the Authority to sell those pharmaceuticals to a licensed wholesale dealer or to any authorised seller of drugs.

12. VALIDITY OF PREMISES REGISTRATION AND PHARMACEUTICAL BUSINESS PERMIT

- 12.1. Every premises registration certificate shall be issued once and it shall not be renewed. Premises registration certificate shall remain valid provided that the following conditions are met;
 - (a) premises start to operate within six (6) months following the approval or registration
 - (b) business permit is renewed
 - (c) The premises have been maintained and remained in conditions which led to its initial registration
 - (d) There is no change of ownership, business name or location.

- 12.2. The permit shall be annually renewed unless suspended, cancelled or revoked by the Authority.
- 12.3. Every permit issued by the Authority shall expire on the 30th Day of June every year.

13. PAYMENT OF FEES

- 13.1. Payment of fees shall be done either through the following ways:-
 - (a) direct to the TFDA zone offices or head quarter
 - (b) TFDA account number 2041100069, NMB, Kariakoo branch for local currency and TFDA account number 02J1021399100, CRDB, Holland house branch, Dar es Salaam, for foreign currency
- 13.2. All bank charges shall be borne by applicants.

14. LANGUAGE

All the prescribed information shall be submitted in English or Kiswahili and all communications regarding the application shall be made in any of these two languages.

15. NOTIFICATION FOR CHANGE OF REGISTERED PREMISES

- 15.1. Any change of location (shift of premises), trade name of the premises, ownership or any other change of registered premises, shall be made to the Director General.
- 15.2. An intention to change location of registered premises shall be made in writings to the Authority before the change is made and the Authority shall notify the applicant on the procedure to be followed.
- 15.3. The Authority shall have final say on the location and name of the proposed premises.

16. REFUSAL OR REVOCATION OF REGISTRATION CERTIFICATE AND PERMIT

- 16.1 The Authority may by giving reasons refuse to register any premises, and may at any time suspend, cancel, revoke or amend premises registration certificate and permit.

17. APPEALS

- 17.1. Any person aggrieved by a decision of the Authority in relation to any application for registration of premises or permit may make representations to the Authority, whereby he shall submit information and arguments to convince the Authority to reconsider its decision.

17.2. After reconsideration of the application, if the Authority still rejects the application, the applicant may appeal to Minister responsible for Health matters.

18. REFERENCE MATERIALS

18.1. The following reference materials shall be made available in the pharmacy:-

- (a) The TFDC Act No. 1 of 2003 and its regulations.
- (b) Tanzania National Formulary
- (c) Good Dispensing Manual (English/Swahili)
- (d) Guidelines for Registration and licensing of pharmaceutical premises
- (e) List of registered drugs with current edition
- (f) Veterinary formulary: Hand book of Medicines used in veterinary Practice

18.2. If possible the following and other relevant reference materials shall be made available;

- (a) Extra Pharmacopoeia (Martindale) current edition
- (b) Merck Veterinary Manual Latest Edition

18.3. The Authority may recommend other reference from time to time.

18.4. Most of these books shall be available at respective Regional Drug Inspectors, TFDA zone offices and TFDA Head office at a nominal fee.

19. ANNEXES

Annex I

Application Forms

Form: **TFDA 0001**

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH AND SOCIAL WELFARE



APPLICATION FOR REGISTRATION OF PREMISES
Section 18 (2) of the Tanzania Food, Drugs and Cosmetics Act, 2003

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 in accordance with the Tanzania Food, Drugs and Cosmetics Act, 2003

1. Name of applicant.....
2. Postal address.....Tel, No.....Fax.....email.....
3. Full name(s) of Partner(s) and Directors(s).....
.....
4. Situated at/lying between Plot /Vessel/ Truck No,
.....Street/Village/Ward.....District/Municipality/City
5. Premises to be registered for the business of
6. The business will be under the supervision of a registered superintendent Mr /Ms /Mrs. /Dr. /
Prof (Full name).....
..... whose qualification is.....
and his/her registration number isof(Year). (Please attach a copy of registration
certificate and acceptance / commitment letter from the proposed superintendent)
7. The proposed name of the premises is

8. If my/our premises is registered and licensed I/We shall keep it in hygienic condition and good state of repair as required under the above mentioned Act and Regulations made there under.

9. I/we have not been convicted at any offence relating to any provision of the Tanzania Food, Drugs and Cosmetics Act, 2003 and Regulations made there under or any other written law related to the business being applied for within 12 months immediately preceding this application and have not been disqualified from holding a license/certificate and my license is/is not suspended.

N.B. False declaration constitutes an offence.

Date.....

Signed.....

Applicant

SECTION B: **DISTRICT/MUNICIPAL/REGIONAL/TFDA INSPECTOR REMARKS**
(Delete which inapplicable)

(In case there is no District Inspector this part should be filled by Regional Inspector)

I (name) Mr. /Mrs./Ms./Dr./Prof.....District/Municipal/Regional/TFDA Inspector of Postal address.....Hereby certify that, I have inspected the above mentioned premises in Section A as per attached inspection checklist and found that it **complies/does not comply** with standards prescribed for registration of premises.

Please give reason(s) if it does not comply

.....
.....
.....

Name of Inspectors(s)	Signatures & stamp	Date
1.
2.....

FOR OFFICIAL USE ONLY

Fees Tshs..... Receipt No.....of.....

Registration granted/not granted because.....

Registration No.....Approved by Management meeting No.....

Of.....

.....
Date

.....
Signature of Director General and stamp.

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH AND SOCIAL WELFARE



APPLICATION FOR PERMIT
Section 20 (1) of the Tanzania Food, Drugs and Cosmetics Act, 2003

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

PART I: APPLICANT INFORMATION

I / We hereby apply for renewal/ a new permit to manufacture, sell, pack, store or distribute the following:

-
1. Name of applicant.....
 2. Postal address.....Tel, No.....Fax.....email.....
 3. Full name(s) of Partner(s) and Directors(s).....
.....
.....
 4. Premises situated at/lying between Plot /Vessel/ Truck No
.....Street/Village/Ward.....District/Municipality/City
 5. Premises registered for the business of
 6. Premises Registration No.....of (year).....
 7. Existing Permit No.....Dated.....Expiring on.....

PART II: APPLICABLE FOR MANUFACTURERS ONLY

I wish to manufacture the following item(s) whose registration status is shown below:

S/N	Common/ Generic Name	Trade Name	Registration No.	For official use only

Use additional sheets of paper if space provided is insufficient.

PART III: APPLICANT DECLARATIONS

1. If my/our business is permitted I/We shall keep the premises in hygienic condition and good state of repair as required under the above mentioned Act and Regulations made there under.
2. I/we have not been convicted at any offence relating to any provision of the Tanzania Food, Drugs and Cosmetics Act, 2003 and Regulations made there under or any other written law related to the business being applied for within 12 months immediately preceding this application and have not been disqualified from holding a license/certificate and my/our license is/is not suspended.

N.B. False declaration constitutes an offence.

Date.....

.....
Signature of **Applicant and stamp**

FOR OFFICIAL USE ONLY

Fees Tshs..... Receipt No.....of.....

Permit granted/not granted because.....

.....

Permit No.....Approved by Management meeting No.....

Of.....

.....
Date

.....
Signature of Director General and stamp

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH AND SOCIAL WELFARE



APPLICATION FOR MEDICAL REPRESENTATIVE'S PERMIT
Section 21 (3) of the Tanzania Food, Drugs and Cosmetics Act, 2003

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

I / We
of.....Postal address.....Tel,
No.....Fax.....and email.....being engaged in
the sale and supply of pharmaceuticals and poisons, hereby make application that our medical
representative
Dr/Mr/Mrs/Ms (full name).....be
Permitted to possess pharmaceuticals and poisons as scheduled below, for the purpose of giving
free samples to persons who may lawfully possess such pharmaceuticals and poisons.

.....
SCHEDULE
.....

.....
.....
.....
.....

Date.....Signed.....
Applicant and stamp

FOR OFFICIAL USE ONLY

Fees Tshs..... Receipt No.....of.....

Permission granted/not granted because.....

Permit No.....Approved by Management meeting No.....of.....

.....
Date

.....
Signature of Director General and stamp

Premises Registration Certificate

**THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH AND SOCIAL WELFARE**



**REGISTRATION CERTIFICATE OF PREMISES
Section 21 (3) of the Tanzania Food, Drugs and Cosmetics Act, 2003**

Premises Registration No.....

This is to certify that the premises owned by M/S of
(Postal Address).....which is located on Block/Vessel/Truck
No..... Situated/lying between
Street, inVillage/Township/Municipality/City, have been
registered to be used as.....
.....for
preparation/selling/packing/carrying/advertising/storing/manufacturing of.....
.....

Subject to the following conditions:-

1. 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, 2003 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.

.....
Date

.....
Signature of Director General and Stamp

N.B: Delete whichever is not applicable

Business Permit

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH AND SOCIAL WELFARE



BUSINESS PERMIT

Section 21 (3) of the Tanzania Food, Drugs and Cosmetics Act, 2003

Permit No.....

Permit is hereby granted to M/Sof
P.O.Box.....to Manufacture/Prepare/Pack/
Sell (Retail/wholesale/Retail & Wholesale)/ Store/ Carry/ Advertise.....
.....a
t the premises situated/lying betweenStreet,
Plot/Block/Vessel/Truck No.....in
.....Village/Township/Municipality/City and with Registration
No.....

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 and Stamp

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.

N.B: Delete whichever is not applicable.

Medical Representative Permit

**THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH AND SOCIAL WELFARE**



MEDICAL REPRESENTATIVES PERMIT

(Section 21 (3) of the Tanzania Food, Drugs and Cosmetics Act, 2003)

Permit No.....

Dr./Mr./Mrs./Miss.....being a Medical representative of is hereby permitted to possess and supply free samples of pharmaceuticals and poisons, specified in the Schedule below, to persons who may lawfully possess such pharmaceuticals and poisons subject to the maintenance of records as required by law.

SCHEDULE

.....
.....
.....
.....

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 and Stamp

CONDITIONS

- 1.** This Permit is not transferable without a written approval of the Authority



THE TANZANIA FOOD AND DRUGS AUTHORITY (TFDA)

INSPECTION CHECKLIST FOR NEW PHARMACEUTICAL PREMISES

(FOR WAREHOUSE/GODOWN, RETAIL, WHOLESALE OR BOTH RETAIL AND WHOLESALE)

(Made under section 18(3) of the Tanzania Food, Drugs and Cosmetics Act, 2003)

*This form must be correctly filled in capital letters and sent to the Director General, TFDA together with application form for consideration on registration of a new premises
Any false information entered in here by inspector(s) may lead the Director General, TFDA to take disciplinary action against the inspector(s)
Only Drug Inspectors as recognised by the Tanzania Food, Drugs and Cosmetics Act, 2003, shall fill in this form.*

PRESCRIBED REQUIREMENTS:

1. Name and address of the pharmacy:

.....
.....

2. Full name of proprietor:

- (i) Individual.....
- (ii) Company.....

.....
Please, attach copy of certificate of company registration (name)/ Memorandum and Articles of Association.....(Yes/No)

3. Name and status of registered superintendent:

- (i) Pharmacist.....Reg. No.....of year.....
- (ii) Veterinary Surgeon (wholesale Veterinary Pharmacy)
.....Reg. No.....of year.....
- (iii) Status of superintendent

4. Location.....

- (i) Plot No, House No, Street/ Hamlet, District and Region.....
- (ii) Distance from nearby pharmacy.....

5. Size of building and number of rooms/compartments:

A. For Retail pharmacy

At least three (3) rooms (i.e. Display room, Dispensing room & Store room)

- (i) Display room.....Present/Not Present
 - Smooth Shelves with sliding glasses.....Present/ Not Present
 - Ceiling Fan/AC.....Present/Not Present
 - Waiting chair(s) for customers.....Present/Not Present
 - Any other (mention).....
- (ii) Dispensing & Store room.....Present /Not Present
 - Air Condition.....Present/ Not Present
 - Lockable shelves for Prescription drugs and controlled substances.....Present/Not Present
 - Presence of source of water and a hand washing basin/sink.....Present/Not Present
 - Provision for sitting desk for superintendent.....Present/Not Present
 - Dispensing window with sliding glass.....Present/Not Present

- Open shelves/pallets.....Present/Not Present
- Strong and secured window.....Present/Not Present
- Refrigerator.....Present/Not Present
- Any Other (mention).....

B. For Wholesale Pharmacy

At least three rooms (i.e Display/Dispatch room, Sales/Record keeping room and Store room)

- (i) Display/Dispatch room.....Present/Not Present
 - Presence of source of water and a hand- washing basin/sink.....Present/ Not Present
 - Ceiling Fan/AC.....Present/Not Present
 - Waiting chair(s) for customers.....Present/Not Present
 - Reception Desk.....Present/Not present
 - Display cabinet with glasses.....Present/Not present
 - Any other (present facility (mention).....
- (ii) Sales/Record keeping room.....Present/Not Present
 - Ceiling fan.....Present/ Not Present
 - Provision for sitting desk for superintendent.....Present/Not Present
 - Lockable shelves for keeping documents.....Present/Not Present
 - Any Other (mention).....

- (iii) Storage room.....Present/Not Present
 - Air Condition.....Present/Not Present
 - Strong door toward storeroom.....Present/Not Present
 - Strong grilled window.....Present/Not Present
 - Open shelves/pallets.....Present/Not Present
 - Confined area for recalled and expired drugs.....Present/Not Present
 - Any other (mention).....

C. For Warehouse/ Godown

- Air Condition sufficient for providing the required cooling condition for respective drugs.....Present/Not Present
- Strong and well secured doors.....Present/ Not Present
- Strong and well secured window.....Present/Not Present
- Open shelves and pallets.....Present/Not Present
- Confined area for recalled and expired drugs.....Present/Not Present
- Any Other (mention).....

6. General external condition of premises

- (i) External surrounding
 - Not direct linked to the bar.....Yes/No
 - Away from source of obnoxious fumes.....Yes/No
 - Away from Damp.....Yes/No
 - Away from open sewage drainage.....Yes/No
 - Any other observed deficiencies.....Yes/No

- (ii) Internal
 - Presence of strong ceiling board.....Yes/No
 - Lighting.....Sufficient/Poor
 - Cooling system.....Sufficient/Poor
 - Durable and smooth floor (easy to clean).....Yes/No
 - Strong and smooth walls (easy to clean).....Yes/No

7. Security of the Premises

- (i) External
 - Provision of adequate barrier.....Yes/No
 - Presence of strong grilled doors and windows.....Yes/No
 - Provision of main entrance double doors; Grilled door outside and glass door inside
.....Yes/No
 - Presence of only one main entrance door.....Yes/No

- Any other present barrier to prevent unauthorized access (mention).....
 - (ii) Internal
 - Provision of suitable lockable storage poisons.....Yes/No
 - Provision for a special cupboard for storage of controlled drugs.....Yes/No
8. Equipment
- (i) Presence of water supply and hand wash basin/ Sink in dispensing room.....
.....Yes/No
 - (ii) Presence of Dispensing measure (beakers, measuring cylinders etc).....
.....Yes/No
 - (iii) Presence of weigh balance and weights.....Yes/No
 - (iv) Presence of mortar and pestle, spatula and dispensing tray.....Yes/No
 - (v) Presence of Hot Plate or any other source of heat.....Yes/No
 - (vi) Source of clean and safe water.....Yes/No
 - (vii) Presence of toilet or nearby accessible toilet.....Yes/No
9. Record Books (To be provided during operation)
- (i) Ledger book or an appropriate inventory control system
 - (ii) Prescription only Medicines Book (Dispensing Book).....Yes/No
 - (iii) Controlled drugs Book.....Yes/No
 - (iv) General sales drugs Book (Both).....Yes/No
 - (v) Expired drugs Book.....Yes/No
 - (vi) Complaints Handling Book.....Yes/No
 - (vii) Visitors Book.....Yes/No
 - (viii) Inspection Reports Register.....Yes/No
 - (ix) Written procedures for maintenance of cold chain products.....Yes/No
 - (x) Recall Book (For Wholesalers).....Yes/No
10. If the Proprietor is not a pharmacist or veterinary surgeon (in case of wholesale veterinary pharmacy), is there any commitment letter or contract agreement.....Yes/No

(Contract agreement is mandatory before the permit is issued; only contract formatted by the authority is accepted)

11. Any other Observation(s).....
.....
.....
12. Inspectors recommendation.....
.....
.....

13. Inspectors declaration

We (names)	(Signatures)	(Date)
(i)
(ii)

Have inspected the above –mentioned proposed site/premises/plan and to the best of our knowledge, we hereby admit that the information we have given is TRUE and CORRECT. We understand that any given false information may lead the Director General, TFDA to take disciplinary action against us.

14. Owner’s Certification

I (Full Name of Owner).....

Certify that my proposed site/premises/plan has been pre-inspected by above named inspectors and I agree with the information provided.

Date.....

Signature of Owner

Registered Premises Inspection Checklist

UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH AND SOCIAL WELFARE

TANZANIA FOOD AND DRUGS AUTHORITY

Tel: +255-22-2450512/2450751

FAX: +255-22-2450793

E-MAIL:Info@tfda.or.tz

Part I Drug Dispensing Outlet Inspection Form (Retail Pharmacies and Wholesalers)

1. General

1.1	Region where the facility is situated (Please select from the list below)			
	Arusha	Kigoma	Mbeya	Rukwa
	Dar es Salaam	Kilimanjaro	Morogoro	Ruvuma
	Dodoma	Lindi	Mtwara	Shinyanga
	Iringa	Manyara	Mwanza	Singida
	Kagera	Mara	Pwani	Tabora
				Tanga
1.2	Name of Outlet			
1.3	Type: (Tick as appropriate):			
	Warehouse	Wholesale	Wholesale/ Retail (Part I)	Retail Part I
1.4	Mailing Address: 		1.5	Physical Address/Location: Street/Ward..... District.....
1.6	Telephone No:		1.7	Fax No:
1.8	E-mail:			
1.9	Premises Licence No.....	1.10 Valid	Y/N	1.11 Is the original licence displayed? Y/N

1.12	Pharmacist in charge:	1.13 Pharmacist Registration Number	1.14 Is the Certificate of Registration displayed?	Y/N
1.15	Date of inspection:		1.16 Date of last inspection:	
1.17	Ownership:	Name of Proprietor(s)		
1.18	If the owner is not a pharmacist, does he/she have a valid contract with a Registered Pharmacist?		Y/N/NA	

2. Personnel

2.1 Responsible Staff (other than the pharmacist in charge)

2.1.1	Name:
2.1.2	Qualification :
2.1.3	Position/Title:

2.2 Sales Person(s):

	2.2.1 Name	2.2.2 Qualifications
1.		
2.		
3.		

3. Type of Inspection

3.1.	Announced/Unannounced: (delete what is not applicable)	3.2	Select one: Routine, Concise, Follow-up, Special, Investigative	3.3	Post-marketing surveillance Y/N If yes, go to 10; if no, go to 4
------	--	-----	--	-----	---

4.	Documents/records keeping				
5.2	In case of non-conformity, explain:	(if space provided is not enough, please use continuation page(s))			

6. Storage conditions

6.1	Is the storage condition suitable for the intended purpose in respect to:				
		Warehouse	Wholesale	Wholesale/ Retail	Retail Part I
1.	Durability of floor and ease of cleaning				
2.	Prevention of infestation by vermin and pests				
3.	Adequate shelving (no medicines are kept on the floor)				
4.	Pallets				
5.	Execution of stock rotation/ FEFO				
6.	Storage of returned/recalled/expired/quarantined goods				
7.	Cold rooms/refrigerators for the storage of vaccines and/or biologicals				
6.2	In case of non-conformity, explain:	(if space provided is not enough, please use continuation page(s))			

7. Ancillary items

7.1	Does the facility do compounding? (If Yes, go to 7.2, if No, skip to next section)	Y/N (Circle)			
7.2	Are suitable ancillary items available for the intended purpose in respect to the follow items:				
		Warehouse	Wholesale	Wholesale/Retail	Retail Part I
1.	Hotplate or any other source of heat				
2.	Weighing balance(s) and weights				
3.	Dispensing measures e.g. measuring cylinders, beakers etc				
4.	Source of clean and safe water				
5.	Mortar and Pestle, spatula and dispensing tray				

7.3	In case of non-conformity, explain:	(if space provided is not enough, please use continuation page(s))
-----	-------------------------------------	--

8. Record-keeping and documentation

8.1	Are record keeping and documentation suitable for intended use in respect to:				
		Warehouse	Wholesale	Wholesale/Retail	Retail Part I
1.	Prescription Book				
2.	Poison Book				
3.	Controlled Drugs Register				
4.	Written procedures for maintenance of cold chain product				
5.	Import Permit				
6.	Ledger Book or an appropriate Inventory Control System				
7.	TFDA endorsed Proforma invoices				
8.	Receipts/Invoices				
9.	Copies of delivery notes				
10.	Accuracy of record keeping				
11.	Do the physical quantities of narcotic/psychotropic drugs MATCH those on the Register				
12.	Are the prescriptions for narcotic/psychotropic drugs written by duly qualified medical personnel and properly kept				
13.	Endorsement of entries by authorized person(s)				
14.	Written procedures for handling returned, recalled and/or expired drugs				
15.	Written procedures for dealing with complaints and/or adverse reaction reports				
8.2	In case of non-conformity, explain:	(if space provided is not enough, please use continuation page(s))			

9. Reference materials

9.1	Are appropriate reference material(s) available?				
		Warehouse	Wholesale	Wholesale/Retail	Retail Part I
1a.	Tanzania National Formulary (TNF)				
1b	Indicate edition of TNF				
2.	Tanzania Pharmaceutical Hand Book				
3.	Tanzanian Food Drug and Cosmetics Act 2003 and its corresponding regulations and guidelines				
4.	Standard Treatment Guidelines				
5.	National Essential Drug List				
6.	Current List of Registered Drugs				
7.	Pharmaceuticals & Poison Act 1978 and its corresponding Regulations & Guidelines				
8.	Good Dispensing Manual (Swahili/English Versions)				
9.	British National Formulary				
10.	British Veterinary Codex				
9.2	In case of non-conformity, explain:	(if space provided is not enough, please use continuation page(s))			

10. Legality of stocked products

Note: In case of major non-conformity, stop inspection, confiscate the products and fill in the confiscation forms

	Y	N	Number of products confiscated
Are there unregistered products stocked in the premises			
Are there unauthorized products on stock			

11. Product Label examination

11.1	Closely examine the products on stock and evaluate the labels in respect to:				
		Warehouse	Wholesale	Wholesale/Retail	Retail Part I
1.	Language of labels and package inserts				
2.	Any signs of tampering				
3.	Labelling requirements				
11.2	In case of non-conformity, explain:	(if space provided is not enough, please use continuation page(s))			

12. Samples for examination

12.1	Conduct physical examination on pharmaceutical products stocked in the facility according to SOP # and take samples of batches of anti-malaria and antibiotic drugs included in the drug quality surveillance program for Minilab screening. In case of suspicious samples, take samples in accordance to PMSP 02-00 or PMSP 02-01.	
12.2	Number of batches of products sampled under the screening program	
12.3	Number of batches of suspicious products sampled	

13. Any Other Observations

(if space provided is not enough, please use continuation page(s))
--

UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH AND SOCIAL WELFARE

TANZANIA FOOD AND DRUGS AUTHORITY

Tel: +255-22-2450512/2450751

FAX: +255-22-2450793

E-MAIL:Info@tfda.or.tz

14.

Recommendations:

Name and Address of Facility

Items requiring attention	Actions agreed to be taken and timeline

15.

Owner's/In-charge Declaration

I/we.....in charge/owner of the said premises,
 certify that, the information and observations made on this sheet during the inspection of the
 premises to be true and correct.

Signature	Date
16. Names of inspectors:	Signature
	Date

**Annex VI
Particulars/Contents**

Dispensing Book

S/n
Date
Patient Name
Product Name
Dose and Dosage
Prescription number
Prescription origin
Quantity dispensed
Batch Number
Name & signature of dispenser
Remarks

Recall Book

Product Name.....

Date of Importation/Purchase.....

Imported/Purchased from.....

Quantity Imported/Purchased.....

Reason for Recall.....

S/n
Date
Pack Size
Sold to
Quantity sold
Quantity recalled/returned
Batch Number
Duration of recall
Name & Signature of the responsible person
Remarks

Expired drugs Register

S/n
Date
Product Name
Expiry date of the product
Dosage form of expired drug
Pack Size
Quantity expired
Batch Number
Name & Signature of the responsible person
Remarks