LEGAL NOTICE NO. ……

THE ZANZIBAR FOOD, DRUGS AND COSMETICS ACT, NO. 2 OF 2006

REGULATIONS
[Made under section 123]

IN EXERCISE of the powers conferred upon me under section 123 of the Zanzibar Food, Drugs and Cosmetic Act, No. 2 of 2006, and upon advice with the Zanzibar Food, Drugs and Cosmetic Board, **I, SULTAN MOH'D MUGHEIRY,** Minister of Health and Social Welfare, do hereby make the following Regulations.

PART I

PRELIMINARY PROVISIONS

Short title and commencement.

1. These Regulations may be cited as the Pharmaceutical Products, Herbal Products, Poisons and Pesticides Regulations of 2009 and shall come into operation on such a date as published in the Official Gazette.

Interpretation.

2. In these Regulations, unless the context requires otherwise:

''Act'' means the Zanzibar Food, Drugs and Cosmetics Act, No. 2 of 2006;

''Advertisement'' includes every form of advertising, whether in a publication, or by the display of any notice or by means of any catalogue, price list, letter, whether circular or addressed to a particular person, or by the exhibition of a photograph or a cinematograph film, or by way of sound recording, sound broadcasting, or television or any other means of communication;

''Board'' means the Zanzibar Food, Drugs and Cosmetics Board established under section 3 of the Act;

''Business'' includes professional practice and any activity carried on by person or a body of persons in relation to products regulated under Act;

''Controlled drugs'' means any narcotic drug, psychotropic substance or precursor as provided under section 78 of the Act;

''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.

''Drug'' includes any medicine, pharmaceutical product or therapeutic substance whether in the form of active ingredient or in the form of preparation;

‘‘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.

‘‘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 or intended to be used to clean pharmaceutical premises facility;

‘‘Herbal drugs’’ means any labeled preparation in pharmaceutical dosage form that contains as active ingredients one or more substances of natur origin that are derived from plants;

‘‘Inspector’’ means an Inspector appointed, authorized or recognized under section 106 of the Act;

‘‘Manufacturer’’ means a person who is engaged in the manufacture, preparation, compounding, processing, packing or labeling of a drug or drugs in industrial scale;

‘‘Minister’’ means the Minister responsible for Health;

‘‘OTC Shop’’ means Over the Counter Medicine shop introduced in the areas where there is no any health facility;

‘‘Permit’’ means a permit issued under these Regulations which shall include renewal of permit to a person to enable him to conduct a business of pharmacy;

‘‘Pesticide’’ any substance or mixture of substances intended for preventing destroying, repelling or mitigating any pest;

‘‘Pest’’ means living organisms that occur where they are not wanted or that cause damage to crops or humans or other animals examples insects, mice, weeds, fungi, microorganism such as bacteria and virus and prions;

‘‘Pharmacist’’ means a person who is registered as a pharmacist in accordance with the provision of the Act;

‘‘Pharmacy’’ means Community pharmacy supervised by a pharmacist;

‘‘Pharmaceutical product’’ means any drug, medicine, medical preparation or therapeutic substance or other article, manufactured or prepared in any way and intended for use by man as a medicine or as a remedy used for the purpose of medical, dental or veterinary treatment;

‘‘Poison’’ means a substance specified in the Poisons List prescribed under section 78 of the Act, includes agrochemicals, and other related substances which are harmful to human being as specified under the Act;

‘‘Prescription medicine’’ means any pharmaceutical required to be sold by retail only upon a prescription given by a duly qualified medical practitioner, dentist or veterinary surgeon;

‘‘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;

‘‘Processing fee’’ means payment charged under the provisions of the Act and these Regulations;

‘‘Products’’ means drugs, poisons, cosmetics and medical devices;

‘‘Products regulated under the Act’’ means Food, Drugs, Cosmetics, Herbal drugs and Medical devices;

‘‘Registrar’’ means Registrar of the Board appointed under section 6 (1) of the Act;

‘‘Sell’’ means sell by wholesale or retail and include import, offer, advertise, keep, expose display, transmit, consign, convey or deliver for sale or authorize, 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;

‘‘Superintendent’’ means any person who is a manager and controls the business of a pharmacist;

‘‘Supervision’’ means activity carried out by a pharmacist in conducting basic management skills in a pharmacy;

‘‘Traditional Practitioner’’ means a person practicing traditional medi who is recognized and approved by the Board;

‘‘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;

"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;

PART II
PROVISIONS ON PREMISES AND LICENCING

Application for registration of premises.

3.-(1) Application for premises registration and permits to operate the business of pharmaceuticals or renewal of permits shall be made in a prescribed application forms as hereunder provided;

(a) Application for registration of Premises under ***SCHEDULE I*** to these Regulations;

(b) Application for Permit under ***SCHEDULE II*** to these Regulations;

(c) Application for renewal of Permit under ***SCHEDULE III*** to these Regulations;

(2) Applicants shall furnish their applications to the head office of the Board in Unguja and Zonal office in Pemba before any construction or renovation is made into the premises.

(3) Applicant shall be required to submit a proof of citizenship from the relevant authorities and in case of a company; at least one share holder must be a Zanzibar.

(4) If the applicant is not a superintendent, he or she shall be required to secure the services of a pharmacist as in-charge of the business. In case of a veterinary medicines business, the in-charge can be either a pharmacist or veterinary surgeon.

(5) 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 the Board for record purposes and attach a copy of registration certificate of the superintendent issued by the Board.

(6) The proposed business name shall be approved by the Board before the applicant forwards it to the Registrar of business names.

Inspection of premises.

4.-(1) The Inspectors shall make sure that the premises applied for registration is inspected to verify if all the requirements have been met.

(2) The Inspectors shall, when conducting the inspection of premises use the inspection checklist for new pharmaceutical premises and give observations and recommendation on the suitability of the premises in the application form.

Approval,

5.-(1) The Board may approve, withhold or reject any application

withhold or rejection of application.

by providing reason(s) for its decision.

(2) All applicants, whose applications have been approved, withhold or rejected by the Board as the case may be, the Board shall within one week from the date in which the decision was made, send with an official letter informing them on the status of their application.

(3) Applicants, whose applications have been withheld for any reasons shall be required to carry out corrective measures before they are legible for reconsideration.

(4) All approved applicants shall be required to pay the annual permit fee as prescribed under these Regulations, before the premises registration certificate and permit to operate the business of pharmaceuticals are granted.

Pharmacy identification name and Permit.

6.–(1) Before starting the business, approved applicants will be required to produce a Pharmacy or OTC Identification name to the office of the Board.

(2). The Board shall issue the appropriate Premises Registration Permit which allows the applicant to start carrying out the business of a pharmacy.

(3) Every permit for the business of pharmacy shall expire on the 31st December every year subject to be renewed.

(4) The renewal shall be done by only filling in the application form for permit and pay the respective annual permit fee prescribed under these Regulations.

(5) Dealers who shall delay to renew their permits beyond 31st January every year shall be required to pay the Board the prescribed annual permit fee together with 25% penalty, contrary to that, registration permit shall be revoked and the premises be closed.

Validity of premise registration and permit.

7.-(1) Every premises registration permit shall be issued once and it shall not be renewed. Premises registration permit 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.

(2) The permit shall be annually renewed unless suspended, cancelled or revoked by the Board.

(3) Every permit issued by the Board shall expire on the 31st Day of December every year.

(4) The Board may by giving reasons refuse to register any premises, and may at any time suspend, cancel, revoke or amend premises registration certificate and permit.

Appeals.

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

(2) After reconsideration of the application, if the Board still rejects the application, the applicant may appeal to the Minister.

Changes or alterations of premises.

9.-(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 Registrar with accompanied fee as prescribed under these Regulations.

(2) Any person who intends to change location of registered premises shall write to the Board before changes have been made and the Board shall notify the applicant on the procedures to be followed.

(3) The Board shall have final say on the location and name of the proposed premises.

Location and design of premises.

10.-(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) 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, and shall be required to address among other issues, the fire prevention facilities.

(3) Premises located within shopping centres, e.g. shopping malls, supermarkets etc, shall be confined and restricted from other activities conducted thereat.

(4) The premises should have a postal address, physical address, telephone number 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.

Design of premises.

11.-(1) 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) The premises should have a sign Board conspicuously displayed and the pharmacy identification logo displayed at the main entrance.

(3) The premises shall be durable, safe and made of permanent building materials so as to protect pharmaceuticals from potential harmful influences.

(4) 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.

(5) The premises shall be equipped so as to provide protection against rodents, birds, vermin etc

(6) The rooms of premises shall be painted with white washable paint with smooth washable finishing.

(7) The surrounding of the premises shall be maintained so as to minimize dust, soil and other contamination to enter the building.

(8) The premises shall have sufficient light and ventilation to enable all operation to be carried out.

(9) Premises shall be sufficiently secured to prevent theft and unauthorized entry and a **"NO SMOKING"** sign should be conspicuously displayed at the entrance.

(10) The premises shall be provided with suitable equipment and facilities for proper storage, safety keeping and handling of pharmaceuticals.

(11) Van for carriage or transportation and selling of the pharmaceutical products shall be of light colour and easily cleaned, dust proof, insulated, ventilated, water tight, covered to prevent direct sunlight and provided with special facilities to maintain cold chain.

(12) 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.

Outlets for compounding.

12. In retail outlets premises 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.

Poisons to be categorized.

13.-(1) Premise providing both human and veterinary drugs, separate displaying shelves and storage cabinets shall be provided for each category.

(2) Premise dealing in pharmaceutical products shall not stock in the same room chemicals or pesticides used exclusively for plant protections.

(3) Premises selling controlled drugs shall have separate secured

cabinets with lock and key for keeping those controlled drugs.

Premises layout.

14.-(1) Retail Pharmacy shall have at least two rooms with clear demarcation and linked to each other for displaying, dispensing and counseling, and shall have one main secured entrance.

(2) The minimum total size or area of the premises shall at least measure $20m^2$ and rooms shall have not less than 2.5m internal height.

(3) The rooms of premises shall 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.

Wholesale premises.

15.-(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, storage and one main secured entrance.

(2) The wholesale premises shall have a minimum total size or area of at least $40m^{2.}$ and rooms shall have not less than 2.5m internal height.

(3) The wholesale premises rooms shall be equipped as indicated in the inspection checklist with adequate shelves and pallets for proper display and storage of medicines respectively.

Retail and wholesale premises.

16.-(1) Premises for both retail and wholesale business shall have at least three rooms namely:

(a) display, receiving and dispatch room;
(b) sales, record keeping and dispensing room; and
(c) the storage room.

(2) The minimum total size or area of premises for wholesale and retail business, shall at least measure $40m^2$ and rooms shall have not less than 2.5 m internal height.

(3) The rooms of premises for wholesale and retail business shall be equipped as indicated in the inspection checklist with adequate shelves and pallets for proper display and storage of medicines respectively.

(4) A clear demarcation of wholesale receiving and dispatch area from the retail part shall be provided to allow orderly receipt or dispatch of pharmaceuticals in bulk.

Provisions for warehouse premises.

17.-(1) Warehouses premises shall be designed and constructed to ensure good storage conditions, sufficient lighting and ventilation.

(2) Warehouses premises shall have sufficient capacity to allow

storage of various categories of pharmaceutical products.

(3) The floor of warehouses premises shall be durable to withstand heavy traffic and loads, the premises shall be provided with well-fitted shelves or pallets.

(4) The premises of warehouses premises shall be equipped with temperature and humidity control facilities or monitors and fire extinguishers.

(5) Warehouse shall be in a condition as indicated in the inspection checklist.

(6) Warehouse shall only be used for storage purposes and sale shall not be allowed.

(7) Warehouse shall not be used as a residential home.

Conditions for storage facilities

18.-(1) Storage facilities shall protect products from deterioration or infestation by vermin and pests. Specified storage conditions shall be monitored and maintained accordingly.

(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.

(3) There should be provision for lockable shelves for keeping controlled substances.

(4) A confined adequate space shall be provided within the premises for storage of returned, recalled, expired, quarantined and substandard or counterfeit pharmaceuticals.

(5) All pharmaceuticals shall be stored off the floor in well – fitted shelves or pallets.

Sanitation and hygiene of premises.

19.-(1) To maintain hygienic working conditions, premises shall have good supply of portable water and proper sink for hand washing.

(2) The premises shall have a toilet or nearby accessible toilet.

(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.

Stock control and handling.

20.-(1) Any undertaking relating to receiving, keeping, selling, dispensing and compounding of pharmaceutical products shall be subject to control by the Board, and all pharmaceuticals shall be properly labeled and stored in suitable and secured places.

(2) Theft and losses of pharmaceuticals shall be reported to police

and Board immediately.

(3) Repackaging and re-labeling of pharmaceuticals are prohibited.

(4) Storage, supply, distribution and recording of controlled drugs and antiretroviral drugs (ARV) must be in accordance with the respective guidelines.

PART III
PROVISIONS ON PHARMACY SUPERVISION AND PERMIT

Personnel in pharmacy.

21.-(1) The pharmacist or veterinary surgeon as the case may be, shall be registered by the Board and shall reside in the locality where the business is carried out.

(2) In addition to sub regulation (1) the veterinary surgeon, may be required to attend a special training course in handling or dispense of pharmaceuticals as approved by the Board.

(3) 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 under good and orderly behaviour;
(v) wear identity badge;

Provisions for supervision of Pharmacy.

22.-(1) Pharmacy shall be supervised by a pharmacist who may be assisted by a pharmaceutical technician or pharmaceutical assistant recognized by the Board.

(2) The owner or superintendent of a pharmacy shall ensure that unqualified personnel who do not possess the prerequisite knowledge do not have access to handling or dispensation of pharmaceuticals.

(3) If the owner is not a superintendent, he shall be made to sign a contract agreement with pharmacist of which among other things shall address the terms of terminations.

(4) Neither the owner or superintendent nor a pharmacist shall terminate such contract agreement without a prior notice to the Board and if the Board is satisfied that the business is not supervised by any pharmacist, that business may be closed.

(5) The superintendent and a pharmacist shall be answerable for conducts of personnel working under their instructions.

(6) Every one pharmacist shall supervise a single pharmacy which is duly registered by the Board in accordance with the provisions of the Act.

(7) The pharmacist shall not act in a similar capacity for any

other body corporate.

(8) The Pharmacist who supervises the Pharmacy as provided under sub regulation (2) of this regulation shall be responsible for anything done in that pharmacy which is contrary to the provisions of the Act.

(9) The Pharmacist must fill the monthly report form of supervision as prescribed in **SCHEDULE IV** to these Regulations and any confiscated medicines shall be listed in **SCHEDULE V** to these Regulations.

Application for registration of premises.

23.-(1) Any person who owns a premises intending to use for manufacturing for sale, sell, and supply or store pharmaceutical products shall apply for registration of that premises to the Board.

(2) For the purpose of this regulation, application for registration of premises shall also include application for renewal premises

(3) Every application for registration or renewal of premises under sub regulation (1) of this regulation shall be made in the form as prescribed in **SCHEDULE I** of these Regulations.

Application for permit to conduct pharmacy business.

24.-(1) Any person who has registered his premises under these Regulations and intend to conduct a business of pharmacy in that premises, shall apply to the Board for permit to conduct a business of pharmaceuticals.

(2) The application made under sub regulation (1) of this regulation shall be in the form as prescribed in **SCHEDULE II** to these Regulations.

Types of Permits

25. For the purpose of these Regulations, there shall be eight (8) types of permits as follows :

(i) Permit for whole sale or retail pharmaceuticals ;

(ii) Permit for wholesale and retail pharmaceuticals;

(iii) Permit for whole sale or retail OTC;

(iv) Permit for wholesale and retail OTC;

(v) Permit for Whole sale or Retail Herbal Medicines;

(vi) Permit for Wholesale and Retail Herbal Medicines;

(vii) Permit for whole sale and retail Verterinary Products.

(viii) Permit for whole sale or retail Verterinary Products.

Issuing of Permit.

26.-(1) If the Board satisfied that the applicant has complied with the requirements as provided in the Act and these Regulations shall be issued a permit in the prescribed form as provided in sub regulation 5 these Regulations.

(2) Permit to sale, supply, and 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 a registered pharmacist who is registered by the Board to supervise pharmaceutical products.

(3) In case of a permit to sell veterinary drugs, shall only be issued or renewed if the person applying for holding such permit is registered pharmacist or registered veterinary surgeon who is registered by the Board to supervise veterinary products.

(4) If the Board becomes dissatisfied with the application of the applicant, may refuse to issue a permit and shall inform in writing the applicant stating the reasons of such refusal.

(5) If the applicant becomes aggrieved by the decision of the Board, may apply to the Minister within seven days (7) from the date of that decision.

Fees.

27. Every registration and permit shall be issued subject with payment of fees as prescribed in the Fee and Charges of these Regulations.

Application period of OTCs.

28. Application period for conducting OTC shops shall commence on 1st November ending 30th November for each year.

Inspection of imported drugs.

29.-(1) Subject to the provision of the Act, the Board shall inspect any imported drugs at the port before authorized to be used in public

(2) In making inspection as provided under regulation (1) of this regulation, an inspector shall fill the Port of Entry (POE) Screening and Testing Form as prescribed in **SCHEDULE VI** of these Regulations.

Power to take sample.

30.-(1) Any inspector may take samples for analysis or for other examination of any drugs, medical devices , cosmetics herbal drugs or of any substance capable of being used in the manufacture of drugs, cosmetics, herbal drug, medical devices which appears to him to be intended for sell or to have been sold for use by human or animal which is found by him on or in any premises ,stall, vehicle, vessel, conveyance, aircraft or place which he is authorized to enter for the purpose of ensuring compliance with the provision of the Act.

(2) An Inspector shall conduct an inspection by taking sample and fill the Sample Receipt Form as prescribed in **SCHEDULE VII** of these Regulations.

(3) An inspector after making an Inspection shall fill the Physical Examination Result Form as prescribed in **SCHEDULE VIII** of these Regulations.

Power to confiscate.

31.-(1) If an Inspector is satisfied that, the sample taken is unfit for intended use, he shall confiscate those products.

(2) In making confiscation as provided under sub regulation (1) of this regulation, the Inspector concerned shall fill the Confiscation Form for Medicines as prescribed in **SCHEDULE V** to these regulations.

Records and documentation.

32.-(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) Dispensing book .....**SCHEDULE IX**
(b) Recall book.....**SCHEDULE X**
(c) Expired drugs Register .....**SCHEDULE XI**

(2) In addition to above records, a person who owns a pharmaceutical business shall maintain a ledger book or an appropriate inventory control system, sales book, inspection reports file complaints handling book and controlled drugs register to be made available to enable traceability of any drug dispensed.

(3) For a wholesale pharmacy, in addition to the requirements given in sub regulation 12 above, shall maintain the following records;

(a) final invoices with corresponding certificate of importation.
(b) copies of delivery notes.

(4) 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.

Reference materials.

33.-(1) The following reference materials shall be made available in the pharmacy:-

(a) Act and its regulations;
(b) Zanzibar 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;
(g) Hand book of Medicines used in veterinary Practice;

(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;
(c) Standard Treatment Guidelines (STG);

(3) The Board may recommend other reference as from time to

time.

(4) Most of these books shall be available at BOARD offices at a nominal fee.

Recall, rejection and withdrawal.

34.-(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 the Board weekly following the directive from the Board and the recall shall be completed within thirty (30) days of the directive.

(2) In case of recall of product initiated by the dealer himself, the Board shall be notified on the reason of recall.

(3) Recall operations shall be capable of being initiated promptly at least down to the level of hospital, dispensary or clinic and pharmacies.

(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.

(5) The disposal of recalled, rejected or withdrawn products from the market shall be effected within one month after completion of exercise.

(6) Disposal exercise shall be carried out under supervision of BOARD inspectors and representatives from other Government Institutions as prescribed in the Disposal Guidelines.

Cessation of business.

35.-(1) The Board 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 Board to revoke the premises registration certificate.

(2) Any permit that has been suspended and or revoked in accordance with the provision of the Act may not be renewed except with the consent of the Board if satisfied with the reasons given by the prior permit holder.

(3) The Board 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.

(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 pharmacist.

(5) Where the pharmacist has given the proprietor a notice, the pharmacist shall continue to supervise the premises and the proprietor shall during those days continue to pay the pharmacist monthly salaries until the end of the notice or any changes within the notice, such notice given either by the proprietor or the pharmacist must be furnished to the Board.

(6) If the proprietor wishes to close down his business because of any reason(s), he shall officially inform the Board in advance, so that the disposal of pharmaceutical products is done under the immediate supervision of the pharmacist.

(7) A business that has been issued with a closure order shall surrender the premises registration certificate and valid permit to the Board.

(8) The Board shall have the responsibility of making follow up to ensure that no registration certificate or permit remain in unauthorized hands.

(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.

(10) If it happens the pharmacist dies, the Board shall give the proprietor a 90 days closure notice to look for another registered pharmacist 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) 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 Board to sell those pharmaceuticals to a licensed wholesale dealer or to any authorized seller of drugs.

PART IV
PROVISIONS ON REGISTRATION OF PHARMACEUTICAL PRODUCTS

Restriction on dealing with Pharmaceutical Products.

36.-(1) Except as otherwise provided in these Regulation, no person shall manufacture, sell supply, import or export any pharmaceutical product unless:

(a) the pharmaceutical product is registered; and

(b) the person holds the appropriate license required and issue by the Board.

Language of pharmaceutical products.

37. All the prescribed information for pharmaceuticals intended to be registered shall be submitted in English or Kiswahili and all communications regarding the application shall be made in any of these two languages.

Provisions for registration of pharmaceutical products.

38.-(1) Applicant shall submit to the Board application for registration of Pharmaceutical Products as specified in **SCHEDULE XII** of these Regulations for each single product intended to be registered.

(2) Every application for registration of a pharmaceutical product shall be accompanied by the processing fee prescribed in these Regulations and by such documents, item drug samples, particulars or information as the Board may require.

(3) The Board may charge any applicant such costs as it may incur for the purpose of carrying out laboratory investigation prior to the registration of any pharmaceutical product.

(4) The processing fee and such costs as may be incurred by the Board under sub regulation (3) of this regulation shall not be refundable in the event of the application being rejected under regulation 8 of these Regulations.

(5) Any change in any document, item, drug sample, particulars or information mentioned in sub regulation (3) shall be notified in writing by the applicant to the Board within fourteen days from the date of such change and shall be accompanied by alternation fee as prescribed in the Fees and Charges section.

(6) The Board may register any Pharmaceutical product subject to such conditions as it may impose.

(7) Subject to sub regulation 8 of this regulations, the period of registration of pharmaceutical product shall be specified in the registration permit issued under sub regulation (7) of this regulation and where so specified the registration shall be valid until the end of the specified period.

(8) Notwithstanding the provision of sub regulation (8) of this regulation, the period of registration of a pharmaceuticals product may be extended upon the end of the specified period for a period of one year, provided that an annual retention fee is paid as prescribed in Part XI on fees and charges regulations.

(9) The period for registered pharmaceutical product shall be five years (5).

Register of Pharmaceuticals.

39.-(1) Subject to sub-regulation (1) of this Regulation, the register shall contain:

a. the name under which the product is registered;
b. the content and quality of the active ingredient;
c. the name and address of the manufacturer;

d. the name and address of the product registration certificate;
e. the registration certificate number; and
f. the date of issue and expiry of the registration certificate if any.

(2) The Board may require any person applying for the registration of any imported pharmaceutical product to furnish a written declaration made by or on behalf of the manufacture of the pharmaceutical product that all the legal requirements governing the manufacture of such product impose by the laws of the country of manufacture have been complied with.

(3) The Board may by providing reason reject any application for registration of any pharmaceutical product.

Rejection of application for registration.

40.-(1) The Board may at any time and by assigning reason(s), suspend or cancel the registration of any pharmaceutical product and may amend the conditions to which such registration relating.

(2) Subject to sub- regulation (1) of this regulation any suspension or cancellation of registration of any pharmaceutical product shall similarly and at the same time affect any permit issued under these Regulations relating to the product.

(3) Notwithstanding sub-regulation (2) where registration granted under these regulations relates to several registered pharmaceutical products the suspension or cancellation of the registration of any product under sub-regulation (1) of this regulation shall not affect the position of other registered pharmaceutical products listed in the permit.

PART V
PROVISIONS ON IMPORTATION OF PHARMACEUTICAL PRODUCTS

Restriction on importation of pharmaceutical products

41- (1) No person, other than a person issued with a permit under the provision of this Regulation may import into Zanzibar any registered pharmaceutical product.

(2) The Board may, issue any of the following permit subject to such conditions it may impose.

(a) A clinical trial *Import Permit of Pharmaceuticals* in the form set out in **SCHEDULE XIII** to these Regulations authorizing the licensee to import any pharmaceutical product for the porposes of clinical trials ,such product must be registered by the Board prior to importation;

(b) An *Import Permit of Pharmaceuticals* set out in **SCHEDULE XIII** to these Regulations authorizing the licence to import and sell or distribute by wholesale or retails, the registered products at the set of premises specified in the Permit.

(c) A clinical trial *Import Permit of Pharmaceuticals* shall include only one product.

(d) A clinical trial Import Permit of Pharmaceuticals shall be valid for such period, not exceeding three years from the date of issue of the Permit and may be specified in the Permit.

(e) Every permit shall be personal to the licensee named therein and shall not be transferable to another person.

(f) Notwithstanding the provision of these Regulation, any bonified tourist or visitor who enters in Zanzibar, any person normally resident of Tanzania mainland, who re-enters in Zanzibar, may bring with him into Zanzibar such quantity of any pharmaceutical product as may be required during a period of twenty –one days for the medical treatment of himself, or any member of the party travelling with him or her.

(g) Any person who fails or refuses to comply with the provisions of this regulation commit an offence.

Application for licence or permit to import pharmaceutical product.

42.-(1) Any person, organization or institution intending to import pharmaceutical products in Zanzibar must fill an application for Importation of Pharmaceutical Products as set in **SCHEDULE XIV** to these Regulations and shall be accompanied by the fee prescribed in the Fee and Charges Regulation.

(2) The applicant for any Import Permit of Pharmaceuticals of any registered pharmaceutical product shall furnish such documents, particulars or information as may the Board require.

(3) The Board, after scrutinizing an application for Import Permit of Pharmaceuticals, may grant an applicant an *Import Permit of Pharmaceuticals* as prescribed in **SCHEDULE XIII** of these Regulations.

(4) Any person who knowing supplies false or misleading information to the Board in connection with his application for any import permit of any pharmaceutical product commit an offence.

Refusal of application for permit.

43.- The Board may, if it thinks fit and by providing reason(s), refuse any application for a permit.

Exemptions.

44.-(1) Any person who wishes to import any product for the purposes of research in a school of pharmacy or a research or training institution or in order to obtain samples for purpose of registration may on applicant be exempted by the Board .

(2) The requirement of Regulation 4 as regards a license to supply or “manufacture” which is necessary for dispensing of any drug for the purpose of its being used for medical treatment by the following persons and in the following circumstances;

(a) pharmacist or a person working under the immediate personal supervision of a pharmacist in a retail pharmacy;

(b) A person acting in the course of his duties who is employed in a hospital or dispensary maintained by the Government, voluntary agency, parastatal organization, charity approved hospitals and registered private hospitals.

(3) A school of pharmacy or any research or training institutions which wishes to manufacture any product for teaching and research purposes may on applicant be exempted by the Board form the provisions of these Regulations.

Directions for recall.

45.-(1) The Board may issue such directions to any persons as it thinks necessary for the carrying out the provision of these Regulations and which may in particular relate to the recall of any product from the market and the disposal of any product.

(2) Any person who contravenes any directions issued by the Board under sub-regulations (1) of this regulation, commit an offence.

PART VI
PROVISIONS ON EXPORTATION OF PHARMACEUTICAL PRODUCTS

Restriction of exportation of registered pharmaceutical products.

46.-(1) No person, other than an authorized local manufacturer of pharmaceutical products may export any pharmaceutical product (other than a pharmaceutical products intended for the medical treatment of himself or his family which is in the possession of the exporter at the time of export) from Zanzibar.

(2) Every authorized manufacturer of registered pharmaceutical products who exports any registered pharmaceutical product shall:

(a) keep a full and accurate record of all such exports; and
(b) if the pharmaceutical product is sent by post it by registered or parcel post.

Application for licence or permit to export pharmaceutical products.

47-(1) Any person, organization or institution intending to export pharmaceutical products outside Zanzibar must fill an *Application for Exportation of Pharmaceutical Products* as set in **SCHEDULE XV** to these Regulations and shall be accompanied by the fee prescribed in the Fee and Charges Regulations.

(2) The applicant for any *Export Permit of Pharmaceuticals* of any registered pharmaceutical product shall furnish such documents, particulars or information as may the Board require.

(3) The Board, after scrutinizing an application for export of pharmaceuticals, may grant an applicant an *Export Permit of Pharmaceuticals* as prescribed i**n SCHEDULE XVI** of these Regulations.

(4) Any person who knowing supplies false or misleading information to i.e Board in connection with his application for any import permit of any pharmaceutical product commits an offence.

PART VII
PROVISIONS ON MANUFACTURING OF REGISTERED PHARMACEUTICAL PRODUCTS

Application for licence to manufacture pharmaceuticals.

48.-(1) Every application for a licence or permit to manufacture registered pharmaceutical products, made pursuant to section 18(1) of the Act, shall be submitted to the Board.

(2) A licence granted under this regulation shall expire on the thirty first day of December of the year in which it is issued.

(3) A licensed manufacturer shall ensure that personnel employed at all levels of manufacture:

(a) posses suitable qualifications required for their jobs;

(b) have adequate experience and are technically competent;

(c) are regularly trained during their employment for the purpose of keeping up to date with any advance or changes; and

(d) are medically examined regularly.

Premises.

49.-(1) A licensed manufacturer shall ensure that, the registered pharmaceutical products are manufactured, processed, packed, labeled and tested in premises which are in accordance with the Good Manufacturing Practices set by the Board.

(2) Subject to sub-regulation (1) of this regulation, a licensed manufacturer shall ensure that:

(a) Adequate storage areas are provided so that all starting rejected or returned materials, intermediate or finished registered pharmaceutical products are adequately separated;

(b) there is a sanitation programme for the maintenance of the premises , records of the premises in good sanitary conditions and records of the performance of the programme is kept at the premises; and

(c) manufacturing premises are maintained in good sanitary conditions

Plant maintenance.

50.-(1) A licensed manufacturer shall ensure that:

(a) manufacturing and testing equipment are designed, placed and

maintained in such a way so as to:

(i) be suitable for the intended use;

(ii) facilitate thorough clearing whenever necessary;

(iii) minimize the risk of confusion or omission of any manufacturing stages and

(b) the manufacturing operations are carried out in accordance with WHO standards of good manufacturing practices rules and other requirements as may be determined by the Board.

Quality control.

51.-(1) a licensed manufacturer shall establish a quality control department under the supervision of a suitable qualified person to control department under the supervision of a suitably qualified person to control:

(a) all materials used in manufacturing process;

(b) the quality aspect of all manufacturing steps; and

(c) the quality and stability of the finished products

(2) For the purpose of sub-regulation (1) of this regulation, a licensed manufacturer shall provide such facilities as may be necessary for the quality Control Department to discharge its duties.

Inspection and maintenance of records

52.-(1) subject to the provisions of these Regulations a licensed manufacturer shall:

(a) conduct regular inspection of his manufacturing and quality control activities and

(b) maintain proper records of every batch of finished pharmaceutical products distributed to enable the complete and rapid recall of the product if necessary.

(2) Any person who refuses or fails to comply with provisions of these regulations commits an offence and upon conviction shall be punished pursuant to the provision of the Act.

Certification of Pharmaceutical products.

53.–(1) The Board may certify on any matter relating to any Pharmaceutical product where such certification is required by any country importing such products.

(2) Subject to sub-regulations (1) of this regulations, a certificate issued under these regulations and shall be subject to fee charged under the fee and charge set under these regulations

Drug information sheets of pharmaceutical products.

54.-(1) Every Pharmaceutical product manufactured locally or imported shall be accompanied with a drug information data sheet detailing the following;

(a) its active substance bearing the international non-proprietary name(INN)

(b) Pharmacological data and describing the Pharmacological effects and mechanism of action

(c) Clinical information describing;

(i) Indications

(ii) dosage regime and relevant pharmacokinetic data;

(iii) contraindications

(iv) precautions and warnings
(v) adverse drug reactions
(vi) drug interactions
(vii) overdose

(d) pharmaceutical information describing :
(i) dosage forms
(ii) Strength of dosage from
(iii) Excipients
(iv) storage conditions and shelf life
(v) descriptions of the products and package
(vi) name and address of manufactures

(2). Every containers of a pharmaceutical product manufactured locally or imported shall be affixed with a label bearing the following information:

(a) the international non-proprietary name (INN) in block letters and trade mark name in small letter in brackets if any:
(b) strength of the dosage unit
(c) the total number of units or volume of container
(d) storage conditions and shelf life
(e) Batch Number
(f) name and address of manufacturer
(g) the word prescription medicine or poison indicating character specified in regulations 9 of this regulations shall:

(i) be printed in red letter on a contrasting background or in letters of some other colour set against a red background.
(ii) be easily legible and either on a separate label or surrounded by a line within which there are no other words.

(3) Directions for the use of any locally manufactured Pharmaceutical product shall be given in English or Swahili languages.

(4) Where the container or a pharmaceutical product is labeled in accordance with the provisions of the Act and of these regulations any outer cover wrapper to that container used only for the purposes of delivery or transport need not be similarly labeled if it complies with the requirements of these Regulations.

(5) Any person who sells any pharmaceutical product not labeled in accordance with the provisions of these Regulations commits an offence.

Indication of character of poison.

55.-(1) Any poison specified in the Act shall be labeled with the words and in the manner specified in these Regulations.

(2) The words specified in sub-regulation (1) shall not be modified by the addition of any other words or marks and shall:

(a) be printed in red letters on a contrasting background or

in letters of some colour set against a red background.

(b) be so printed as to be easily legible on a separate label or surrounded by a line within which there are no other words.

Refusal to grant licence.

56.- The Board shall not grant a license to an applicant unless the applicant complies with the requirements of these Regulations.

PART VII

PROVISIONS ON DISPOSITION OF PHARMACEUTICAL PRODUCTS

Control on sell of registered pharmaceutical products.

57.-(1) Subject to the provisions of this Regulation, no person may sell by retail any registered pharmaceutical product specified as a prescription medicine in the List of Poisons to except on and in accordance with the terms of a prescription given by dully qualified medical practitioner, dentist or veterinary surgeon in the form provided for by sub-regulation (5) of this regulation.

(2) Any person who sells any such prescription medicine in contravention of the provision of this regulation commits an offence.

(3) Notwithstanding the provision of sub- regulation (1) of this Regulation, where an authorized seller of prescription medicine has reasonable cause to believe that a person ordering any prescription medicine in the Fourth Schedule to these Regulations is a dully qualified medical practitioner, dentist or veterinary surgeon and who is by reason of some emergency unable to furnish him with the prescription immediately, he may, not withstanding that no prescription with in twenty four hours next following deliver the prescription medicine ordered in accordance with directions of that person.

(4) Notwithstanding sub-regulation (2) of this regulation, the supply of prescription medicine shall not be repeated unless the prescription has been given.

(5) Any person by whom any undertaking reference to in sub-regulation (3) of this regulation in accordance with the undertaking and who for the purposes of obtaining delivery of any prescription medicine under sub regulation (2) of this regulation makes a statement which is to his knowledge false commits an offence.

(6) For the purposes of this Regulation shall:

(a) be in writing and signed by the person giving it with his usual signature and dated by his;

(b) specify the address of the person giving it;

(c) specify the name and address of the person for whose treatment it is given, or if the prescription is given by a veterinary surgeon, of the person in charge of the animal to

which the medicine is to be administered;

(d) have written it, if given by a dentist, the words “for dental treatment only”;

(e) specify the total amount of the medicine to be supplied and, except in the case of a preparation which is to be used for external treatment only, the dose to be taken.

(7) A person dispensing the prescription shall comply with the following requirements:

(a) the prescription shall not be dispensed more than once unless the prescribes has directed on it either that it may be dispensed at stated intervals or a stated number of times.

(b) if the prescription contains a direction that it may be dispensed, stated number of times or at started intervals, it shall not be dispensed otherwise than in accordance with the directions;

(c) a prescription which contains a direction that it may be stated number of times but no direction as to intervals at which it may be dispensed, shall not be dispensed more than once three days, and a prescription which contains a direction that it is to be dispensed at started interval but no directions to dispensed at started number of times that it may be dispensed, shall be dispensed more than three times;

(d) at the time of dispensing or, where a prescription medicine has been delivered in accordance with the provisions of sub regulation (2) of this regulation, on the subsequent receipt of the prescription, there shall be noted on the prescription, above the signature of the prescribe, the name and address of the seller and the date which the prescription was dispensed;

(e) except in the case of a prescription which may be dispensed again, the prescription shall for sell a period of two years be retained and kept on the premises on which it was dispensed in such manner as to be readily available for inspection.

(8) Any person who refuses or fails to comply with the provisions of sub regulation (8) of this regulation commits an offence.

Indications on Pharmaceutical products.

58.-(1) A person shall not sell any liquid poison, other than medicine for the treatment of human ailments, in bottles unless the bottle is labeled with the words “NOT TO BE TAKEN” and also the words *“ SIYA KUNYWA’*

(2) A person shall not sell any embrocation, liniment, lotion, liquid antiseptic or other liquid medicine for external application which contains a poison unless the container is labeled with the name of the article and the words, in capital letters “ FOR EXTARNAL USE ONLY”,

and the words *"KWA MATUMIZI YA NJE TU SI YA KUNYWA"*

(3) A person shall not sell any hydrocyanic acid or cyanic unless the container is labeled with the words "WARNING", this container holds a poison substance and should be open and used only by persons having expert knowledge of the precautions to be taken in its use, and the words *"HATARI" kuna sumu kali sana ndani, usifungue wala kutumia kama huna maelekezo ya Mtaalam".*

(4) Any person who fails to comply with any of the provisions of this regulation commits an offence.

Restrictions on sell of acids.

59.-(1) Every person dealing in Part II poison shall be conversant with the relevant provisions of the Act these Regulations concerning the manner of handling and otherwise dealing with those poisons.

(2) Every person intending to deal with Part II Poison shall appear before the Registrar or his assistant who shall interview him with a view of satisfying himself that the persons conversant with the relevant provisions of the Act and these Regulations as provided under sub regulation (1).

(3) The relevant provisions are those relating to the labeling of container and articles of poison, restrictions on sales by licensed sellers of Part II poisons, regulations relating to indication of characters of poisons, safe custody of poisons and direction for use, and regulation relating to transportation of poisons.

(4) The Registrar or his Assistant Registrar after interviewing any person intending to deal with Part II poisons, shall recommended whether or not that person may be issued with a permit.

Control of licensed sellers Part II poisons.

60.-(1) A person may sell Part II poisons only in premises licensed for that purpose.

(2) The premises for selling Part II poisons shall secure enough the safe custody of poisons.

(3) In the case of a seller of veterinary, agricultural and horticultural poisons and certain commonly used bulk poison, adequate secure storage space must be available.

(4) Any set of premises which does not or fails to fulfill the requirements of this regulation shall not be granted registration.

Premises where Part II poisons sold to be secured

61.-(1) No applicant for any application for a business of Part II poisons in respect of any area already adequately served by another permit holder operating in that area shall be issued with a permit.

(2) In case of medicinal Part II poisons, no consideration shall be given to an application for a business of medicinal Part II poison in area already served by Public Outlets.

No further license or permit in area already secured.

62.-(1) Where a person is convicted of an offence under the Act, such conviction shall entail automatic revocation of his license or permit and shall be ground for refusal to renewal the license or permit in the following period.

(2) No permit which has been revoked in the accordance with the provisions of these regulations may be renewed except with the express authority of the Board.

A license to be revoked in case of conviction.

63. A person given a permit to sell poison Part II of the Poisons List shall not sell;

(a) any poison except in a closed container as closed by the manufacturer of other person from whom the poison was obtained;

(b) any poison in Group A of Part II of the Poison List, for which a special use in indicated , or in Group B of a Part II of the Poison List, unless in addition to the normal labeling requirements, is labeled with a notice of the special purpose.

Restriction on sales by licensed sellers Part II Poisons.

64.-(1) Any poison in a group B of Part II of the Poison List unless the purchaser is engaged in the trade or business of agriculture and requires the poison for the purpose of hat trade or business.

(2) Any person who refuses or fails to comply with the provisions of sub regulations (1) of this regulation commits an offence.

Transport of poison.

65.(1) A person shall not consign for transport any poison specified in the fifth schedules to these regulation unless the outside of the poison is labeled conspicuously with the name of description of the poison and a notice indicating that it is to be kept separate from food and from empty food container.

(2) A person shall not knowingly transport any poison specified in the fifth schedule to these Regulation in any vehicle in which food is being transported unless the food is carried in a part of the vehicle effectively separated from the containing the poison, or is otherwise adequately protected from the risk of contamination.

(3) Any person who refuses or fails to comply with any of the provisions of this regulation commits an offence.

PART VIII
PROVISIONS ON ADVERTISEMENT OF PHARMACEUTICAL PRODUCTS

Permit for advertisements of Pharmaceutical

66.-(1) A person shall not advertise any pharmaceutical product unless he/she obtained a permit from the Board.

(2) Every advertisement should be submitted to the Board for scrutiny before made public and there will be a fee as prescribed in

products. Fees and Charges Regulations.

Application for advertisements of herbal products.

67.-(1) The Board shall impose fees for every advertisement pharmaceutical, that fees may be varied from time to time as the Bo may think fit.

(2) Any person who makes any advertisement contrary to th Regulations, commits an offence and shall be liable to a fine of not than three hundred thousand shillings.

PART IX
PROVISIONS ON ADVERTISEMENT OF HERBAL PRODUCTS

Fee for advertisement.

68.-(1) Any traditional practitioner who wants to advertise treatments shall make an application in writing to the Board.

(2) Any application made under sub rule (1) of this regulation, shall accompanied with the followings:

(a) name of the traditional practitioner;
(b) address of his office which includes:

(i) telephone numbers; or
(ii) postal address; or
(iii) e-mail address; or
(iv) Website.

(2)Every advertisement should be submitted to the Board for scrutiny before made public and there will be a fee as prescribed in Fees, Charges and Penalties Regulations.

Restriction on promotion pharmaceutical products.

69.-(1) The Board shall impose fees for every advertisement in rela to traditional treatment, that fees may be varied from time to time as th Board may think fit.

(2) Any traditional practitioner who makes any advertisement contra to these Regulations, commits an offence and shall be liable to a fine of more than three hundred thousand shillings.

PART X
PROVISIONS ON PROMOTION OF PHARMACEUTICAL PRODUCTS

Issuence of permit for Medical Representatives.

70. (1) A person shall not promote pharmaceutical products except in accordance with the Code of Conduct for Promotion as provided in the regulations.

(2) 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 recognized institution or any other approved knowledge by Board.

(3) Any person who intends to engage in drug promotion shall make

an application to the Registrar.

(4) Applications shall be subject to payment of fees as provided under the Fees and Charges Regulations.

(5) Applicants shall ensure that all related profession credentials are attached to the application form.

(6). The Board shall then issue the Medical Representative permit in which allows the applicant to start carrying out the business of a Medical Representative.

PART XI
PROVISIONS ON PESTICIDE CHEMICALS

Label of pesticides products.

71.-(1) Every registered Pesticide shall have a label written in understandable language (English or Swahili)

(2) For small containers, the label shall

(a) Contain trade and chemical names, Batch no. date of manufacture/expiry, first and emergency aid information.

(b) A leaflet containing the entire label information as specified under the provision made under the Act will be enclosed in the package.

(3) All labels and warning signs shall be written in legible and indelible letters.

(4) All warning signs shall appear in bold letters and shall contain appropriate warning symbols or pictograms and colour codes.

(5) The label shall contain accurate information and free from any statement, which cannot be substantiated, or which could falsely inform a purchaser or user.

(6) The label shall not describe a product by such terms as “harmless/ not toxic”.

Restriction on pesticides advertisement.

72.-Every advertisement shall substantiate technical information and shall not contain any visual presentation which direct or by implication, omission, ambiguity or exaggerated claim is likely to mislead the buyer or public.

Compliance on transportation of pesticides

73.-(1) Every transporter, importer, exporter producer, warehouse operator, dealer in pesticides shall.

(a) take appropriate measure to ensure the safety of employees, premises, facilities, public and the environment in accordance to the existing Nation, International or foreign standards.

(b) ensure the creation of awareness on the inherent risks of

indiscriminate use and misuse of pesticide.

(c) conduct occupational health programs and sustain maintenance of safety working gears and

(d) provide, appropriate antidote and facilities to effect fist aid.

(2) Every transporter, Importer, Exporter, Producer, warehouse operator, dealer in Pesticides shall keep records of:-

(a) type of pesticide.
(b) origin.
(c) port of entry.
(d) quantities received/sold/transported/sorted.
(e) uses.
(f) batch number.
(g) date of manufacture/ importation/ Exportation.
(h) past accidents, spill, incidences and their dates if any.
(i) emergency aid information.

(3) The information kept under regulation 4 shall be:

(a) Reported annually to Board.
(b) Maintained for at least 5 years.
(c) Made available to inspectors whenever requested.

Permit for importation of pesticides.

74.-(1) Every importer of Pesticides shall apply for a Pesticides Importer Permit from the Board as prescribed in **SCHEDULE XVII** to these Regulations.

(2) Every importer shall pay a proceeding fee of 2% of the FOB of the value of the pesticide imported.

(3) A person applying to import a pesticide shall submit a sample of that pesticide before issuance of the permit.

(4) The Board may require a Pesticide being imported to contain a Certificate of Analysis from the country of origin.

(5) The importer of Pesticide shall notify the Registrar by giving details of the consignment and parties involved.

(6) Upon arrival to the port of entry the consignment shall be inspected and sample taken accordingly and analyzed before being allowed into the country.

Permit for exportation of pesticides.

75.-(1) Every exporter shall obtain a Permit for Exporting Pesticide from the Board as prescribed in **SCHEDULE XVIII** to these Regulations.

(2) Every exporter shall pay a processing fee of 2% of the FOB of the value of the pesticide.

(3) The exporter shall notify the Registrar by giving details of the consignment and parties involved.

(4) A person applying to export pesticide shall submit a sample of the pesticide to be exported for quality verification before issuance of the permit.

(5) The Board may require a Pesticide being exported to contain a Certificate of analysis from a designated laboratory.

Provision for pesticides manufacturer.

76.-Every Pesticide manufacturer shall take all appropriate measures to :-

(i) Ensure the safety and health of their employees the plant, the public and the environment in accordance to National and foreign standard.
(ii) Inform, instruct, supervise and train employees on safety and health aspects for safe performances.
(iii) Monitor the exposure of the employees in the work place for comparison with national exposure standards.
(iv) Treat/dispose of the Pesticide waste generated during production process in accordance with national standard guidelines and procedures approved by Board before discharge to environment/water bodies.
(v) Set and adhere to code of practice and guidelines on the safe use and handling of pesticides.
(vi) Submit samples to the Board for each batch for quality assessment.
(vii) Ensure that the raw materials used in production are registered by the Board and the pesticides produced are those accept by the Board.

Approval of pesticides packages.

77.-(1) Every package of a Pesticide shall be approved by the Board unless directed otherwise by the same.

(2) Package of Pesticide shall be sufficiently durable to provide maximum protection during storage, handling, transporting, stacking, loading and unloading and shall protect pesticide from deterioration, volume and weight changes and be able to accommodate accumulation of gas in ambient temperatures.

(3) Packing shall have labels as specified under sub regulation (1) of this regulation.

PART XII
FEES, CHARGES AND PENALTIES.

Fees, Charges and Penalties.

78.-(1) The following fees shall be paid in connection with matters arising under the Act:

(i) Registration for manufactures, importers, retailer and wholesaler of food..... 30,000/=TZS;

(ii) Permit for manufactures, importers, importation, retailer and wholesaler of food..... 20,000/=TZS;

(iii) Permit for manufacturing, retail, wholesale and storing premises..... 20,000/=TZS;

(iv) Food import fees..... 0.5%FoB(TZS);

(v) Cosmetic import fees.....1%FoB (TZS);

(vi) Pharmaceuticals, Herbal and medical devices import fee..... 2%FoB (TZS);

(vii) Health Certificate for exportation..... 10,000/=TZS;

(viii) Penalty for violation of import fees..... 5%FoB (TZS);

(ix) Registration of new pharmacy (wholesale and retail) ..... 30,000/=TZS;

(x) Inspection of new premises..... 20,000/=TZS;

(xi) Forms for application and permit..... 5,000/= TZS;

(xii) Permit for opening a new wholesale OTC..... ..... 70,000/=TZS;

(xiii) Permit for renewal of a wholesale OTC.....70,000/=TZS;

(xiv) Permit for opening a new retail OTC.....70,000/=TZS;

(xv) Permit for renewal of a retail OTC.....50,000/=TZS;

(xvi) Permit for opening a new Pharmacy.....100,000/=TZS;

(xvii) Permit for renewal of a wholesale Pharmacy.100,000/=TZS;

(xviii) Permit for opening a new retail Pharmacy.....70,000/=TZS;

(xix) Permit for renewal of a retail Pharmacy.....70,000/=TZS;

(xx) Change of name (Pharmacy, OTC or Veterinary shop)..... 20,000/=TZS;

(xxi) Penalty for delaying of renewal of Permit (beyond 31st /January every year).....25% (TZS) plus prescribed annual fee.

(xxii) Registration fees for Pharmacist, Pharmaceutical technicians and Pharmaceutical

assistant.....25,000/=TZS;

(xxiii) Advertisement fee..... 30,000/= TZS;

(xxiv) Registration of traditional healers.....30,000/=TZS;

(xxv) Permit for traditional healers.....20,000/=TZS;

(xxvi) Permit for importation of traditional medicines.....20,000/=TZS;

(xxvii) Registration of finished Pharmaceutical products imported into Zanzibar.....250 USD;

(xxviii) Registration of Pharmaceutical products manufactured in Zanzibar.....100 USD;

(xxix) Registration of Pesticides.....100 USD;

(xxx) Annual retention fee (should be paid on 31st /January) or before end of each year.....100USD;

(xxxi) Registration of Pharmaceutical products imported in Zanzibar and relabeled and/or repacked locally.....200USD;

(xxxii) Alterations of registration in respect to the original application, or registration certificate for foreign and local manufacturers..... 250 USD;

(xxxiii) Any copy of certificate of registration..... 20USD;

(xxxiv) Application for Clinical Trial 500USD;

(xxxv) The Board may charge applicant such costs it may incur for any purposes as specified under the Act.

Payment of fees.

79.-(1)Payment of fees shall be done either through the following ways:-

(a) Direct to the Board offices.

(b) Board account number 021103000579 Peoples Bank of Zanzibar (PBZ) Malindi Zanzibar.

(c) Board account number 04110000060 Peoples Bank of Zanzibar (PBZ) Chake Chake.

(2) All bank charges shall be borne by applicants.

PART XII

MISCELLANEOUS PROVISIONS

General penalty.

80.-(1) Any person convicted of an offence under any of the provisions of these Regulations shall be liable to a fine not less than one million and exceeding five million shillings or imprisonment for a term not exceeding two years or both such fine and imprisonment.

(2) The Board may revoke any permit, and may refuse to grant or renew any permit or licence issued or assumable under these Regulations.

(3) Any Person aggrieved by the revocation of a permit or licence, or the refusal to grant or renew a permit or licence, by the Board, may subject to the provisions of section 117 of the Act appeal to the Minister.

SCHEDULE I

ZANZIBAR REVOLUTIONARY GOVERNMENT
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD, DRUGS & COSMETICS BOARD

All correspondence should be addressed to:
The Registrar,
Zanzibar Food, Drugs and Cosmetics Board,
P.O. Box 3595,
Zanzibar
Tel/Fax: +255-2233959
E-Mail: znBoard@yahoo.com
Website: zanhealth.info/Board

BOARD FORM NO: 3

APPLICATIONS FOR REGISTRATIONS OF PREMISES

[Made under regulation 3(1)(a)]

In accordance with the provisions of sections 16 of the Food, Drug and Cosmetics Act No 2 of 2006 applicant are required to fill the following:
I / We hereby apply for registration of my/our existing/ new premises in accordance with the Zanzibar Food, Drugs and Cosmetics Act, No2 of 2006;

1. Name of applicant……
2. Full name(s) of Partner(s) and Directors(s)……
3. Postal Address: ……**TEL NO:**……
4. E-mail……
5. Shehia……District……
Wishing to carry on a business of ……
(manufacturing/storage/distribution/selling) do hereby apply for registration of Premises situated at
……
6. Name of my shop……

7. Premises to be registered for the business of Wholesale/ Wholesale &Retail/Retail/Storage

8. The business will be under the supervision of ……
whose qualification is……
and his/her registration number is ……of …… (Year). (Please attach a copy of registration certificate and acceptance / commitment letter from the proposed Supervisor)

7. 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 Zanzibar Food, Drugs and Cosmetics Act, No 2 of 2006 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 permit and my permit is/is not suspended.

N.B. False declaration constitutes an offence.

…… **……**
Date **Signature of Applicant**

SECTION B: FOR OFFICIAL USE ONLY
Fees Tshs: 20,000/= Receipt No……of……
Registration granted/not granted because……
Registration No……
Approved by BOARD - Secretariat.

…… **……**
Date **Signature of Registrar and stamp.**

SCHEDULE II

ZANZIBAR REVOLUTIONARY GOVERNMENT
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD, DRUGS & COSMETICS BOARD

All correspondence should be addressed to:
The Registrar,
Zanzibar Food, Drugs and Cosmetics Board,
P.O. Box 3595,
Zanzibar
Tel/Fax: +255-2233959
E-Mail: znBoard@yahoo.com
Website: zanhealth.info/Board

BOARD FORM NO: 1

APPLICATION FOR PERMIT TO SELL, WHOLE SALE/WHOLESALE &RETAIL/RETAIL OF PHARMACEUTICALS
[Made under regulation 3(1)(b)]

I / We (Name of Applicant).....
Full name(s) of Partner(s) and Directors(s).....

Hereby apply for a Permit to sell WHOLESALE/WHOLESALE &RETAIL/RETAIL (Poisons I, Over The Counter Medicines (OTC), Veterinary Medicines) for the year.....
in accordance with the Zanzibar Food, Drugs and Cosmetics Act, No2 of 2006 and regulations.
(In case of OTC as per attached list).
Postal Address: .....**TEL NO:**.....

E-mail.....

My shop is located at: .....

Shehia.....District.....

NAME OF PHARMACY/OTC/VETERINARY SHOP..........
The registered Pharmacist Incharge for control of the distributions of **Poisons I** is
DR/MR/MS.....
Registration Number.....

Health Personnel (s) who will be dispenser(s) of medicines at my Pharmacy/OTC/Veterinary shop is/are:

1. .....(Attach copy of Certificate)

2. .....(Attach copy of Certificate)

N.B. False declaration constitutes an offence.

..... **.....**
Date **Signature of Applicant**

For official use only:
Application Accepted/Rejected.....
(In case of rejection reasons for rejection).....
.....
Date.....Signature and stamp of the Registrar.....

SCHEDULE III

ZANZIBAR REVOLUTIONARY GOVERNMENT
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD, DRUGS & COSMETICS BOARD

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Website: zanhealth.info/Board

BOARD FORM NO: 2

APPLICATION FOR RENEWAL OF WHOLESALE/WHOLESALE & RETAIL/RETAIL PHARMACEUTICAL DEALER'S PERMIT

[Made under regulation 3(1)(c)]

I / We (Name of Applicant).....
Full name(s) of Partner(s) and Directors(s).....
Hereby apply for renewal of Permit to sell WHOLESALE/WHOLESALE &RETAIL/RETAIL (Poisons I, Over The Counter Medicines (OTC), Veterinary Medicines) for the for the year.....
in accordance with the Zanzibar Food, Drugs and Cosmetics Act, No2 of 2006 and regulations.
(In case of OTC as per attached list).
Postal Address: .....**TEL NO:**.....

E-mail.....

My shop is located at: .....

Shehia.....District.....

NAME OF PHARMACY/OTC/VETERINARY SHOP..........
The registered Pharmacist Incharge for control of the distributions of **Poisons I** is
DR/MR/MS.....
Registration Number.....

Health Personnel (s) who will be dispenser(s) of medicines at my Pharmacy/OTC/Veterinary shop is/are:

1. .....(Attach copy of Certificate)
2. .....(Attach copy of Certificate)

N.B. False declaration constitutes an offence.

..... **.....**
Date **Signature of Applicant**

For official use only:
Application Accepted/Rejected.....
(In case of rejection reasons for rejection).....
.....
Date.....Signature and stamp of the Registrar.....

SCHEDULE IV

ZANZIBAR REVOLUTIONARY GOVERNMENT
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD, DRUGS & COSMETICS BOARD

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BOARD FORM NO. 13

DRUG PREMISES INSPECTION FORM
[Made under regulation 22(9)]

General

1.1	Name of Outlet						
1.2	Type : (Tick as appropriate):						
	1.2.1	1.2.2	1.2.3	1.2.4	1.2.5	1.2.6	1.2.7
	Warehouse	Wholesale	Retail Part I	Retail Part II	Hospital	Health centre	Dispensary

1.3	Mailing Address:	1.4	Physical Address/Location:
	.....		.....
	.....		.....
	.....		.....

1.5	Telephone No.	1.6		Fax No. .....
1.7	E- mail			
1.8	Date of inspection	1.9		date of last Inspection: .....

		1.10.1	1.10.2
1.10	Ownership	Government/Private/NGO (delete what is not applicable)	(Specify type) ..... (In case of private indicate name of owner or proprietor (s)

1.11	If the owner is not a pharmacist, does he/she have a valid contract with a Registered Pharmacist?				Y/N	
1.12	Premises Licence No		1.13 Valid	Y/N	1.14 Is the original Licence displayed?	Y/N
1.12	If not explain:					

2. Type of Inspection (Tick as appropriate)

2.1	Routine:		2.2	Concise:		2.3	Follow up:	
2.4	Investigative:		2.5	Announced/Unannounced: (delete what is not				

				applicable)				

3. 0 Personnel

3.1 Responsible Staff

3.1.1	Name:	……
	Qualification:	……
	Position/Title:	……

3.2.1 Sales Person(s):

	3.2.1 Name	3.2.2 Qualifications
1.		
2.		
3.		
4.		

4.0 General condition of premises

4.1	Is the premise appropriate for the intended purpose in respect to:					
		Ware house	wholesale	Retail PI	Retail II	Hosp/Disp
1	Layout					
1.	Size/Number of rooms					
2.	Hygiene					
3.	State of repair					
4.	Ventilation & Cooling system					
5.	Lighting					
6.	Display of drugs					
7.	Utilities: water, hand wash basins, WC					
4.2	In case of non-conformity, explain:	(If space provided is not enough, please use continuation page(s)				

5. Security of premises

S/N	Is the premises secure in respect to:					
		Ware house	wholesale	Retail PI	Retail II	Hosp/Disp
1.	External Perimeter security e.g fencing, gates, walls, window etc					
2.	Special secure cupBoards for restricted drugs e.g. controlled drugs					
3.	Accessibility to unauthorized person(s)					
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

S/N	Is the premises secure in respect to:					
		Ware house	Wholesale	Retail PI	Retail II	Hosp/Disp
1.	Durability of floor and ease of cleaning					
2.	Prevention of infestation by vermin and pests					
3.	Adequate shelving					
4.	Pallets					
5.	Execution of stock rotation/FEFO					
6.	Storage of returned/recalled/expired/quarantined					
7.	Cold rooms/refrigerator for the storage of vaccines and/or biological					
6.2	In case of non-conformity, explain:	(If space provided is not enough, please use continuation page(s)				

7. Ancillary items

7.1	Are suitable ancillary available for the intended purpose in respect to the follow items:					
		Ware house	Wholesale	Retail PI	Retail II	Hosp/Disp
1.	Hotplate or any other source of heat					
2	Weighing balance(s) and weights					
3.	Dispensing measuring cylinders, beakers etc					
4.	Source of clean and safe water					
5.	Mortar and Pestle, spatula and dispensing tray					
7.2	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:					
		Ware house	Wholesale	Retail PI	Retail II	Hosp/HC/Disp
1.	Prescription Book					
2	Poison Book					
3.	Controlled Drugs Book					
4.	Written procedures for maintenance of cold chain product					
5.	Import Permit					
6.	Ledger Book or an appropriate inventory Control System					
7.	BOARD endorsed Proforma invoices					
8.	Receipts/Invoices					
9.	Copies of delivery notes					
10.	Accuracy					
11.	Endorsement of entries by authorized person(s)					
12.	Legality of the source(s) of supplies					
13.	Written procedures for handling returned, recalled and/or expired drugs					
14.	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. Label examination

9.1	Is the product suitable for intended use in respect to					
		Ware house	Wholesale	Retail PI	Retail II	Hosp/Disp
1.	Language of labels and package inserts					
2	Any signs of tempering					
3.	Labeling requirements					
9.2	In case of non-conformity, explain:	(If space provided is not enough, please use continuation page(s)				

10. Sample for examination (use Sample receipt form)

11 Reference materials

11.1	Are record keeping and documentation suitable for intended use in respect to:					
		Ware house	Wholesale	Retail PI	Retail II	Hosp/HC/Disp
1.	Zanzibar National Formulary (Current Edition)					
2.	Tanzania Pharmaceutical Hand Book					
3.	Standard Treatment Guidelines					
4.	Zanzibar Essential Medicine					

	List					
5.	Current List of Registered Drugs					
6.	Zanzibar Food and Drug Act and its corresponding Regulations & Guidelines					
7.	Good dispensing Manual (Swahili/English Versions)					
8.	British National Formulary					
9.	British Veterinary Codex					
10.	In case of non-conformity, explain:	(If space provided is not enough, please use continuation page(s)				

12. Any other Observations

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

13. Recommendations:

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

14. Owner's /In – charge Declaration

1/We …… in charge/owner of the said premise, certify that, the information and observations made on this sheet during the inspection of the premises to be true and correct.
Signature ……

Date……

15. Names of inspectors: Signature

- ……
- ……
- ……

Date: ……

SCHEDULE V

ZANZIBAR REVOLUTIONARY GOVERNMENT
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD, DRUGS & COSMETICS BOARD

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BOARD FORM NO: 11

CONFISCATED DRUGS FOUND AT THE PREMISE CONTRARY TO THE LAW TAKEN AS EXHIBIT/SAMPLE

[Made under regulation 22(9)]

DATE ……TIME ……

NAME OF THE PREMISES _____

LIST OF DRUGS CONFISCATED/TAKEN BY INSPECTORS

No.	NAME	UNIT	QUANTITY	No.	NAME	UNIT	QUANTIYT
1.				11.			
2.				12.			
3.				13.			
4.				14.			
5.				15.			
6.				16.			
7.				17.			
8.				18.			
9.				19.			
10.				20.			

PARTICULARS

I /we _____ Owner/In charge of the Premises of the above named premise/dispensary, confirm that the drugs listed above have been confiscated/taken by Inspectors

Signature of the Owner/In charge ……

INSPECTORS NAME	SIGNATURE
……	……
……	……
……	……

SCHEDULE VI

ZANZIBAR REVOLUTIONARY GOVERNMENT
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD, DRUGS & COSMETICS BOARD

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BOARD FORM NO: 11

PORTS OF ENTRY (POE INSPECTION, SCREENING AND TESTING FORM

[Made under regulation 29(2)]

(A rejoinder to SOP for Inspection and testing of Drug at Ports of Entry (POE)

Particulars in this checklist must be scored for every consignment imported into the country:

POE Name …… Name of Consignee ……

Product particulars

S/N	Product names	S/N	Product names

(A) Summary

1	2	3	4	5
Consignment OR "R" Number	Date &Time inspection started	Date & Time inspection completed	Status; Release/Rejected (indicate as appropriate upon conclusion of the inspection and testing)	Initials or Signature of Inspector

(B) Documentation

1	Instructions	Result /Decision (Tick Y for yes or N for no. Unless otherwise specified. If no wri "DETAINED)		
(a)	Does the consignee have Proforma Invoice (P1) and endorsement by the (IC) with the original endorsement by the Pharmacy Board(PB)? If yes proceed to (c) below	Y	N	
(b)	Are the specified product imported from sources indicated in the PI/IC? If yes , proceed to (c) below	Y	N	
(c)	Is the consignment being imported through the declared POE?	Y	N	
	If yes enter the PI and IC numbers and proceed to #2 below:	IP/IC no: Date:		
2.	Is the Clean Report of Findings CRF/Final Classification and Valuation Report (FCRV0/IDF? receipt date within the expiry	Y	N	

	date of the PI/C? If yes , record the date of receipt and proceed to #3 below.			
3.	Are the exporter and importer named in the CRF/Final Classification and Valuation Report (FCVR) the same as those listed in the PI? If yes, proceed to item # below.	Y	N	

Proforma with be valid for 6 months from date of endorsement by the PB
"[2] DETAINED" Means: (1) stop inspection, (2) complete Rejection /Detention From, (3_ Inform the TRA/C&E of the rejection/detention, (4) give a copy of the TRA , Rejection/Detention from to TRA
"If detention issues are resolved by written instructions from the PB, proceed from where the inspection stopped"

4.	Does the FOB value of the CRF/FCV/IDF MATCH the PI? If yea proceed to item #5 below.	Y	N	
(a)	Do the items description and the quantities for each of the products indicate in the CRF/FCVR MATCH the quantities authorized in the PI? If yes, proceed to item #5 below.	Y	N	If no see 4b and 4c below
(b)	Are the item description and quantities indicated in the CRF GREEATER THAN authorized in the PI? If yes, detain consignment.	Y	N	If no see 4c below
(c)	Are the item description and quantities indicate in the CFR LESS THAN authorized I the PI? If yes, mark the quantities of short landed items on the PI and the word " and proceed to tem # 5 below.	Y	N	
5. Review the Certificate of Analysis (COA) to determine:				
	Is the COA signed and stamped by authorized person(s) If yes, proceed to (b) below:	Y	N	
	Ate the reported test results within specification limits? If yes, proceed to (b) below:	Y	N	
	For products with more than 24 months shelf life do they have 60% of their shelf life remaining? If yes or not applicable, proceed to (d) below.	Y	N	
	For the products with less tan 24 months shelf life, do they have 80% of their shelf life remaining/ If yes, proceed to Section C below for further verification of the consignment.	Y	N	

(C) Physical Examination and Testing

1.	Is there Certificates Analysis for each batch? If yes, proceed to item#2.	Y	N	
2.	Does the label show any evidence of tampering/ if not, proceed to #3	Y	N	
3.	Is the language written on the label and package insert ia Swahili and of English? If the language is correct and package insert is available, proceed to #4.	Y	N	
4.	Do the expiration dates on the unit samples and the COAs match? If yes, proceed to #5	Y	N	
5.	Do the batch numbers on the unit examples and the COAs match? If yes , proceed to #6	Y	N	
6.	Do unit samples collected from each batch, have tamper-proof seals? Are the seals intact? If both are yes, proceed to 7	Y	N	
	Are the samples required for testing? If yes, proceed to Section C items #10-14 of SOP#?	Y	N	If no proceed to section D below to conclude the inspection.

SECTION D: Conclusion

The consignment and tested as required is hereby:	Status (tick as appropriate)	**Remarks (if any)**
1. Released:		
2. Rejected:		Reasons for rejection must clearly indicated:

Name of Inspector: …… Signature …… Date ……

SCHEDULE VII

ZANZIBAR REVOLUTIONARY GOVERNMENT
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD, DRUGS & COSMETICS BOARD

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BOARD FORM NO: 14

SAMPLE RECEIPT FORM
[Made under regulation 30(2)]

1. Name of Institution/Company (under inspection)

2. Address .....

3. Date of inspection /collecting sample .....

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

.....

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

6. Size of Lot from which sampled.....

7. Name and address of Manufacturer .....

.....

8. Batch No. .....Manufacturing Date.....Expiring Date .....
Place sampled (Port of entry, Manufacturing plant, Wholesale/Retail Pharmacy, Part II Shop, etc.) .....

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

.....

10. Collectors Identification on Seal .....

11. Name of Representative (s) of the Inspected Establishment.	Signature	Date.
(1).	.....	.....

12. Name of Drug Inspector(s)
Signature

(Sampling Officer)	Signature	Date
(1)	.....	.....
(2)	.....	.....

SCHEDULE VIII

ZANZIBAR REVOLUTIONARY GOVERNMENT
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD, DRUGS & COSMETICS BOARD

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BOARD FORM NO: 15

PHYSICAL EXAMINATION RESULTS FORM
[Made under regulation 30(3)]

This form is a rejoinder to SOP # PBQCL 10 for Physical Examination of Samples of Pharmaceutica Dosage Forms)

Name of Consignee/Facility .....

Consignment # (incase of PoE) .....

A. Product particulars.

SN	NAME OF PRODUCTS	BATCH NO	SN	NAME OF PRODUCT	BATCH NO

B. Test Results and Observations: Tablets/ Capsules

	Parameter	Specification(s)	Status		Results/ Other Observations
			Pass	Fail	
1.	Odour (on immediately on opening the outer and immediate container:	No odour, except for flavored tablets and those with active ingredients normally having characteristic odour.			
2.	Odour (after exposing the tablets according to recommended plan of exposure):	No odour, except for flavored tablets and those with active ingredients normally having characteristic odour.			
3.	Uniformity of size(visual inspection)	Uniform in:size.			
4.	Uniformity of shape:	Uniform in shape.			
5.	Uniformity colour:	Uniform in colour.			
6.	Colour of tablets/capsules in bottle(in case of glass container)	Uniform in colour.			
7.	Uniformity of coating (can be film coated, sugar coated, or enteric coated);	Uniform			
8.	Tablet core fully covered:	Uniform coating with core fully covered.			
9.	Polishing	Uniform polished and free of adhering fine powders			
10.	Markings (scoring, letters etc)	Uniform and identical			
11.	Breaks	Free of breaks			
12.	Cracks	Free of cracks			
13.	Splitting	Free of splitting			
14.	Capping or cavitations	Free of capping or cavitations			
15.	Embedded surface sports or	Free of embedded surface sports and			

	contamination	contamination			
16.	Foreign particulate contamination	free from foreign particulate contamination			
17.	Evidence of embedded or adherent foreign matters	Free of any evidence of embedded or adherent foreign matters			

18.	Pinholes	Free of pinholes in capsules			
19.	Presence of empty capsule	Free of empty capsules			
20.	Presence of open or broken capsules	Free of open or broken capsules			
21.	Presence of weak points in body of capsules	Free of weak points			
22.	Capsule not intact; cap separate from body	Capsule intact			
23.	Stickiness	Non-stick			
24.	Container /bottle free of extraneous material	Container /bottle free of extraneous material			
25.	Other (specify)				

C. Test Results and Observations: Solution and Suspension Dosage Forms

1	**Parameter**	**Specification(s)**	**Status**		**Results/ Other Observations**
			Pass	Fail	
2	(a) Particulate matter:	Liquid (syrups and solutions) should be entirely free from foreign particles.			
	(b) clarity	The liquid/solution should be clear and free from turbidity			
	Liquid solutions and pareteral dosage forms				
3		Easily dispersed to obtain a homogenous suspension upon moderate shaking for 20 seconds.			
4		Remain homogenous for at least 3 minutes.			
5		Injected aqueous suspension should flow freely without binding when the contents of vial/ampoule are aspirated through a 22-gauge. 1 inch hypodermic needle, using a suitable volume hypodermic syringe			
6		Non-aqueous injectable suspensions should flow freely without binding when the contents of the vial/ ampoule are aspirated through 18- gauge, 1-11/2 inch hypodermic needle using a suitable volume hypodermic syringe.			
7	State of primary container	Should not show any evidence of cracks, break, tears and leakage.			

Conclusion/decision

The sample as visually inspected:		Status (tick as appropriate)	**Remarks (if any)**
1.	Passes:		
2.	Fails:		
Name of Inspector ……		Signature ……	Date ……

SCHEDULE IX

ZANZIBAR REVOLUTIONARY GOVERNMENT
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD, DRUGS & COSMETICS BOARD

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BOARD FORM NO: 65

DISPENSING BOOK
[Made under regulation 32(1)(a)]

PARTICULARS /CONTENTS

S/N	DATE	PATIENT NAME	DOSE & DOSAGE	PRESCRIPTION NUMBER	PRESCRIPTION ORIGIN	QUANTITY DISPENSED	BATCH NO.	NAME AND SIGNATURE OF DISPENSER	REMARKS

SCHEDULE X

ZANZIBAR REVOLUTIONARY GOVERNMENT
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD, DRUGS & COSMETICS BOARD

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BOARD FORM NO: 66

RECALL BOOK
[Made under regulation 32(1)(b)]

Product name……
Date of importation /Purchase ……
Imported / Purchased from ……
Quantity imported/Purchased……

Reason for Recall……

PARTICULARS/ CONTENTS

S/N	DATE	PACK SIZE	SOLD TO	QUANTITY SOLD	QUANTITY RECALLED/RETURNED	BATCH NO.	DURATION OF RECALL	NAME AND SIGNATURE OF THE RESPONSIBLE PERSON	REMARKS

SCHEDULE XI

ZANZIBAR REVOLUTIONARY GOVERNMENT
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD, DRUGS & COSMETICS BOARD

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BOARD FORM NO: 67

EXPIRED DRUGS REGISTER
[Made under regulation 32(1)(c)]

PARTICULARS/ CONTENTS

S/N	DATE	PRODUCT NAME	EXPIRY DATE OF THE PRODUCT	DOSAGE OF EXPIRED DRUG	PACKEGE SIZE	QUANTITY OF EXPIRED DRUGS	BATCH NUMBER	NAME AND SIGNATURE OF THE RESPONSIBLE PERSON	REMARKS

SCHEDULE XII

ZANZIBAR REVOLUTIONARY GOVERNMENT
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD, DRUGS & COSMETICS BOARD

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BOARD FORM NO: 53

APLLICATION FOR REGISTRATION OF PHARMACEUTICALS

[Made under regulation 38(1)]

{For official use only} Date..... Application No..... .....

PRODUCT PARTICULARS

1. Proprietary name
1.1 Name of the active ingredient(s) (International Non-proprietary Name in English)
1.2 Pharmacotherapeutic classification (Anatomic- Therapeutic Classification system)
2. Pharmaceutical Dosage form
2.1 Route of administration
2.2 Container, closure and administration devices
2.3 Package sizes 2.4 Shelf life 2.5 Shelf life (after first opening of container) 2.6 Shelf life (after reconstitution) 2.7 Storage conditions
2.8 ☐ Narcotic or ☐ Psychotropic ☐ Prescription only ☐ Pharmacy only ☐ General sale ☐ Other information

3. Details of applicant (who must be the future holder of the marketing authorization / registration certificate)

Name:

Business Address:

Postal Address:

Country:

Phone: Fax: Email:

3.1 Details of a locally responsible person (who must be nominated by the applicant and submit evidence of power of attorney)

Name:

Business Address:

Country:

Phone: Fax: Email: -

3.2 Manufacturer(s), site(s) and authorized person(s) for the pharmaceutical dosage form

NAME (Attach WHO certification of each)	ACTIVITY	SITE (Business Address, Phone and Country)	AUTHORIZED PERSON
			Name: Business Address:

Source (manufacturer) of active pharmaceutical ingredient(s):

Name:

Street Address:

Business Address:

Country:

Phone: Fax: Email:

4. Status of marketing authorization/registration in the country of origin and authorization/registration number and date where applicable -

5. Registration status for this medicine in the SADC member states and in other countries

Registered:	Country: Date of authorization: Authorization number: Trade name:
Pending:	Country: Date of submission: Application number:
Rejected:	Country: Date of rejection: Application number: Reason for rejection:
Withdrawn (by applicant before registration)	Country: Date of withdrawal: Reason for withdrawal: Trade name:

Withdrawn (by applicant after registration)	Country: Date of withdrawal: Reason for withdrawal: Trade name:
Suspended/Revoked/Withdrawn (by competent authority)	Country: Date of withdrawal: Reason for withdrawal: Trade name:

6. Proposed indications of the product

7. Complete composition per dosage unit

Name (INN) of	Reason for inclusion	Quantity	Unit of measure	Referenced monograph
- API				
1.				
2.				
3., etc.				
- Excipients				
1.				
2.				
3., etc. -				

8. Declaration by an applicant

I, the undersigned certify that all the information in this form and all accompanying documentation is correct. I further certify that I have examined the following statements and I attest to their correctness: 1. The current edition of the WHO guideline on **"Good Manufacturing Practice for Pharmaceutical Products"**, and/or equivalent national guideline, is applied in full in all premises involved in the manufacture of this medicine.

2. The formulation per dosage form correlates with the master formula and with the batch manufacturing record.

3. The manufacturing procedure is exactly as specified in the master formula and batch manufacturing record.

4. Each batch of all starting materials is either tested or certified (in accompanying certificate of analysis for that batch) against the full specifications in the accompanying documentation and must comply fully with those specifications before it is released for manufacturing purposes.

5. All batches of the active pharmaceutical ingredient(s) are obtained from the source(s) specified in the accompanying documentation.

6. No batch of active pharmaceutical ingredient(s) will be used unless a copy of the batch certificate established by the manufacturer is available.

7. Each batch of the container/closure system is tested or certified against the full specifications in the accompanying documentation and complies fully with those specifications before released for the manufacturing purposes.

8. Each batch of the finished product is either tested, or certified (in an accompanying certificate of analysis for that batch), against the full specifications in the accompanying documentation and complies fully with release specifications before released for sale.

9. The person releasing the product is an authorized person as defined by the WHO guideline **"Good Manufacturing Practices: Authorized person – the role, functions and training"** and/or an equivalent Tanzania guideline.

10. The procedures for control of the finished product have been validated for this information. The assay method has been validated for accuracy, precision, specificity and linearity.

11. All the documentation referred to in this certificate is available for review during GMP inspection.

12. Clinical Trials were conducted in accordance with Good Clinical Practice, where applicable. -

I also agree that:

1. The holder of marketing authorization/registration certificate is obliged to follow Zanzibar requirements for handling adverse reactions of its products.

2. The holder of registration certificate is obliged to follow Zanzibar requirements for handling batch recalls of its products.

Name:……

Qualification:……

Position in the company:……

Signature:……

Date:…… **Official stamp:** -

N.B. False declaration constitutes an offence.

…… ……

Date **Signature of Applicant**

For official use only:

Application Accepted/Rejected……

(In case of rejection reasons for rejection)……

……

Date……Signature and stamp of the Registrar……

SCHEDULE XIII

ZANZIBAR REVOLUTIONARY GOVERNMENT
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD, DRUGS & COSMETICS BOARD

All correspondence should be addressed to:
The Registrar,
Zanzibar Food, Drugs and Cosmetics Board,
P.O. Box 3595,
Zanzibar
Tel/Fax: +255-2233959
E-Mail: znBoard@yahoo.com
Website: zanhealth.info/Board

BOARD FORM NO: 63

IMPORTATION PERMIT OF PHARMACEUTICAL PPRODUCTS
[Made under regulation 41(2)]

I, REGISTRAR,
Being the person in-charge with the administration of the law relating to the Control of Pharmaceutical Products to which the Zanzibar Food, Drugs and Cosmetics Act, No.2 of 2006,hereby certify that I have approved the importation of pharmaceuticals in Zanzibar by ……
P.O. Box ……..TEL NO……
E-Mail……
ZANZIBAR granted by the Board to engage in business of pharmaceuticals under
Permit No……Proforma Invoice No ……of (date/month/year)……

The specified product shall be imported by supplier……

Subject to the condition that:

(i) This certificate is valid for the importation of the specified products, on one occasion only;

(ii) The certificate shall, until otherwise extended, expires on ……

(iii) The consignment shall be imported by Air/Sea/port of ……

(iv) The imported consignment will be subjected to inspection at the port of entry by authorized BOARD inspector before release.

S/n	Item Description (trade /generic)	Pack Size	Quantity
1.			
2.			
3.			
4.			
5.			

(See attached list)

I am satisfied that the consignment proposed to be imported is solely for medical Purposes

…… **……**

Date **Signature and stamp of Registrar**

SCHEDULE XIV

ZANZIBAR REVOLUTIONARY GOVERNMENT
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD, DRUGS & COSMETICS BOARD

All correspondence should be addressed to:
The Registrar,
Zanzibar Food, Drugs and Cosmetics Board,
P.O. Box 3595,
Zanzibar
Tel/Fax: +255-2233959
E-Mail: znBoard@yahoo.com
Website: zanhealth.info/Board

BOARD FORM NO: 18

APPLICATION FOR IMPORTATION OF PHARMACEUTICALS, HERBAL MEDICINES & POISONS

[Made under regulation 42(1)]

Name of Applicant.....
of (postal address).....Tel No.....
Undertaking Pharmaceuticals/Herbal medicines/Poisons business of wholesale/Retail/manufacturing/ Others
(specify).....
Hereby apply for *Importation Permit for Pharmaceutical Products* in Zanzibar.
Permit No..... Issued on .....
Location of business .....
Name Pharmacist Incharge.....
Registration number.....

PURPOSE OF IMPORTATION PERMIT
(tick where is applicable)

- □ Raw materials and /or packaging materials pro production of Pharmaceuticals for human use medicines.
- □ Raw materials and /or packaging materials pro production of pharmaceuticals for veterinary use medicines.
- □ Finished pharmaceutical products for human use medicines.
- □ Finished pharmaceutical products for veterinary use medicines
- □ Clinical trials of specified products (only one product per application)

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

DECLARATION

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

Signature of Applicant ..... Stamp.....

FOR OFFICIAL USE ONLY	
Received by	Signature ..... Stamp .....

SCHEDULE XV

ZANZIBAR REVOLUTIONARY GOVERNMENT
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD, DRUGS & COSMETICS BOARD

All correspondence should be addressed to:
The Registrar,
Zanzibar Food, Drugs and Cosmetics Board,
P.O. Box 3595,
Zanzibar
Tel/Fax: +255-2233959
E-Mail: znBoard@yahoo.com
Website: zanhealth.info/Board

BOARD FORM NO: 45

APPLICATION FOR REGISTRATION AS PHARMACEUTICALS EXPORTER

[Made under regulation 47(1)]

Name of Applicant.....
of (postal address).....Tel No.....
Undertaking Pharmaceuticals/Herbal medicines/Poisons business of wholesale/Retail/manufacturing/ Others
(specify).....
Hereby apply for *Exportation Permit for Pharmaceutical Products* from Zanzibar for the year .....
Permit No..... Issued on .....
Location of business .....
Name Pharmacist Incharge.....
Registration number.....

PURPOSE OF EXPORTATION PERMIT

(tick where is applicable)

- □ Raw materials and /or packaging materials pro production of Pharmaceuticals for human use medicines.
- □ Raw materials and /or packaging materials pro production of pharmaceuticals for veterinary use medicines.
- □ Finished pharmaceutical products for human use medicines.
- □ Finished pharmaceutical products for veterinary use medicines
- □ Clinical trials of specified products (only one product per application)

DECLARATION

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

Date of application .....

Signature of Applicant ..... Stamp.....

FOR OFFICIAL USE ONLY	
Received by	Signature ..... Stamp .....

SCHEDULE XVI

ZANZIBAR REVOLUTIONARY GOVERNMENT
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD, DRUGS & COSMETICS BOARD

All correspondence should be addressed to:
The Registrar,
Zanzibar Food, Drugs and Cosmetics Board,
P.O. Box 3595,
Zanzibar
Tel/Fax: +255-2233959
E-Mail: znBoard@yahoo.com
Website: zanhealth.info/Board

BOARD FORM NO: 46

REGISTRATION PERMIT FOR EXPORTATION OF PHARMACEUTICAL PPRODUCTS

[Made under regulation 47(3)]

I REGISTRAR,

Being the person in-charge with the administration of the law relating to the Control of Pharmaceutical Products to which the Zanzibar Food, Drugs and Cosmetics Act, No.2 of 2006,hereby certify that I have approved the exportation of pharmaceuticals in Zanzibar by ……
P.O. Box ……TEL NO……
E-Mail……
Permit is hereby granted by the Board to engage in business of pharmaceuticals exportation under
Permit No……of (date/month/year)……

The specified product shall be imported by supplier……

Subject to the condition that:

(i) This certificate is valid for the exportation of the specified products, on one occasion only;

(ii) The certificate shall, until otherwise extended, expires on ……

(iii) The consignment shall be exported by Air/Sea/port of ……

(iv) The exported consignment will be subjected to inspection at the port of entry by authorized BOARD inspector before release.

S/n	Item Description (trade /generic)	Pack Size	Quantity
1.			
2.			
3.			
4.			
5.			

(See attached list)

I am satisfied that the consignment proposed to be exported is solely for medical Purposes

……. **……**

Date **Signature and stamp of Registrar**

SCHEDULE XVII

ZANZIBAR REVOLUTIONARY GOVERNMENT
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD, DRUGS & COSMETICS BOARD

All correspondence should be addressed to:
The Registrar,
Zanzibar Food, Drugs and Cosmetics Board,
P.O. Box 3595,
Zanzibar
Tel/Fax: +255-2233959
E-Mail: znBoard@yahoo.com
Website: zanhealth.info/Board

BOARD FORM NO: 57

IMPORTATION PERMIT OF PESTICIDES CHEMICALS
[Made under regulation 74(1)]

I, REGISTRAR,
Being the person in-charge with the administration of the law relating to the Control of Pharmaceutical Products to which the Zanzibar Food, Drugs and Cosmetics Act, No.2 of 2006,hereby certify that I have approved the importation of Pesticides Chemicals in Zanzibar by ……
P.O. Box ……TEL NO……
E-Mail……
ZANZIBAR granted by the Board to engage in business of Pesticides Chemicals under
Permit No……Proforma Invoice No ……of (date/month/year)……

The specified product shall be imported by supplier……

Subject to the condition that:

(i) This certificate is valid for the importation of the specified products, on one occasion only;

(ii) The certificate shall, until otherwise extended, expires on ……

(iii) The consignment shall be imported by Air/Sea/port of ……

(iv) The imported consignment will be subjected to inspection at the port of entry by authorized BOARD inspector before release.

S/n	Item Description (trade /generic)	Pack Size	Quantity
1.			
2.			
3.			
4.			
5.			

(See attached list)

I am satisfied that the consignment proposed to be imported is solely for intended purposes.

…… ……

Date **Signature and stamp of Registrar**

SCHEDULE XVIII

ZANZIBAR REVOLUTIONARY GOVERNMENT
MINISTRY OF HEALTH AND SOCIAL WELFARE

ZANZIBAR FOOD, DRUGS & COSMETICS BOARD

All correspondence should be addressed to:
The Registrar,
Zanzibar Food, Drugs and Cosmetics Board,
P.O. Box 3595,
Zanzibar
Tel/Fax: +255-2233959
E-Mail: znBoard@yahoo.com
Website: zanhealth.info/Board

BOARD FORM NO: 59

REGISTRATION PERMIT FOR EXPORTATION OF PESTICIDES CHEMICALS
[Made under regulation 75(1)]

I, REGISTRAR,
Being the person in-charge with the administration of the law relating to the Control of Pharmaceutical Products to which the Zanzibar Food, Drugs and Cosmetics Act, No.2 of 2006,hereby certify that I have approved the exportation of Pesticides Chemicals in Zanzibar by ……
P.O. Box ……..TEL NO……
E-Mail……
Permit is hereby granted by the Board to engage in business of Pesticides Chemicals under
Permit No……..of (date/month/year)……

The specified product shall be exported by supplier……

Subject to the condition that:

(i) This certificate is valid for the exportation of the specified products, on one occasion only;

(ii) The certificate shall, until otherwise extended, expires on ……

(iii) The consignment shall be exported by Air/Sea/port of ……

(iv) The Pesticides Chemicals to be exported shall be subject to inspection at the port of entry by authorized BOARD inspector before release.

S/n	Item Description (trade /generic)	Pack Size	Quantity
1.			
2.			
3.			

(See attached list)

I am satisfied that the consignment proposed to be exported is solely for intended purposes.

……. **……**

Date **Signature and stamp of Registrar**

SIGNED on …… day of February, 2009.

(SULTAN MOH'D MUGHEIRY)
MINISTER OF HEALTH AND SOCIAL WELFARE.

…… February, 2009;
ZANZIBAR.