

GOVERNMENT NOTICE NO. .... published on .....

THE TANZANIA FOOD, DRUGS AND COSMETICS ACT  
(CAP. 219)

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REGULATIONS  
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*(Made under section 26 and 122(1) (c))*

**THE TANZANIA FOOD, DRUGS AND COSMETICS  
(REGISTRATION AND LICENSING OF PREMISES FOR VETERINARY PRODUCTS)  
REGULATIONS, 2018**

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(REGISTRATION AND LICENSING OF PREMISES FOR VETERINARY PRODUCTS)  
REGULATIONS, 2018**

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## ARRANGEMENT OF REGULATIONS

### PART I

#### PRELIMINARY PROVISIONS

Citation	1. These Regulations may be cited as the Tanzania Food, Drugs and Cosmetics (Registration and Licensing of Premises for Veterinary Products) Regulations, 2018 and shall come into operation on the date of publication in the Government Gazette.
Scope of application	2. These Regulations shall apply in registration and licensing of premises dealing with manufacturing and wholesaling of veterinary products including medical devices in Tanzania Mainland.
Interpretation	3. In these Regulations, unless the context otherwise requires:- “Act” shall have the same meaning ascribed to it under section of the Act “Agricultural implements” cover ploughs, threshers, axes, powrahs, chaffcutter machine, cultivators, seed drills, etc. These implements are used for agriculture work to improve the efficiency and reduce the labour. A large variety of agricultural implements are also used as attachments to tractors. “Authority” shall have the same meaning ascribed to it under section of the Act  “Business permit” means annual dealer’s permit or permit issued to owner of the outlet for veterinary medicines authorizing to operate the business of veterinary products; “Controlled drugs” shall have the same meaning ascribed to it under section of the Act “Feeds” means any edible material that provides nutrients to the animal, “Fertilizers” means any material of natural or synthetic origin (other than liming materials) that is applied to soils or to plant tissues to supply one or more plant nutrients essential to the growth of plants, Cap. 219 “Inspector” shall have the same meaning ascribed to it under section of the Act; Cap.219 “Manufacture” shall have the same meaning ascribed to it under section of the Act; “Minister” shall have the same meaning ascribed to it under section of the Act Cap. 319 “Para-professional” means any person enrolled as paraprofessional under the Veterinary Act, Cap. 319 “Para-professional assistant” means any person enlisted as paraprofessional assistant under the Veterinary Act, “Permit” means any license granted under the Act, Cap.133 “Pesticide” means any plant protection substance intended for preventing, destroying or controlling pest, unwanted species of plant or animal causing harm during or otherwise interfering with the production, processing, storage, transport, or marketing of food, agricultural commodities, wood and wood products. The term includes substances intended for use as a plant growth regulator, defoliant, desiccant or agent for thinning fruit or preventing the premature fall of fruit and substances applied to crops either before or after harvest to protect the commodity from deteriorating during storage and transport, “Pharmaceutical product” shall have the same meaning ascribed to it under section of

	the Act;
Cap. 311	“Pharmacist” means a person who is registered as a pharmacist under the Pharmacy Act,
Cap. 311	“Pharmaceutical assistant” means a person enlisted under the Pharmacy Act;
Cap. 311	“Pharmaceutical technician” means a person enrolled under the Pharmacy Act;
	“Premises” means any entity dealing with manufacturing or wholesaling of veterinary products;
	“Prescription” means a lawfully written direction by a veterinarian for the preparations and dispensing veterinary medicine by a veterinarian;
GN.63 of 2015	“Prescription only medicine” means any veterinary medicines as prescribed in the seventh Schedules of Tanzania Food Drugs and Cosmetics (Scheduling of medicines) Regulations, 2015
Cap. 319	“Retail veterinary business” means a business which consists of or includes the retail sale of veterinary products as recognized by Veterinary Act;
Seed Act No.18 of 2003	“Seed” means that part of plant which is or is intended to be used for propagation and includes any true seed, any vegetative material including seedling, corm, cutting, bulb, bulbil, layer, marcott, root, runner, scion, set, split, stem, stock, stump, sucker or tuber so used or intended to be so used;
	“Superintendent” means a person who manages and controls the business of a wholesaling or manufacturing of veterinary products;
Cap. 319	“Veterinarian” shall ascribe the meaning of section 3 of the Veterinary Act;
	“Veterinary medical device” means an instrument, apparatus, implement, medical equipment, machine, contrivance, in vitro reagent or similar or related article, including any component, part or accessory, which is
	(a) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease in animals or;
	(b) intended to affect the structure or any function of animal body and which does not achieve any of its principal intended purposes through chemical action within the body of animals and which is not dependent upon being metabolized for the achievement of any of its principle intended purpose.
	“Veterinary medicine” means any substance or mixture of substances manufactured, sold or presented for use in:-
	(a) the diagnosis, treatment, mitigation or prevention of disease, disorder, abnormal physical or mental state, or the symptoms thereof, in animal;
	(b) restoring, correcting or beneficial modification of organic or mental function in animal; or
	(c) article intended for use as a component of any articles specified in clause (a) or (b); but does not include medical devices or their components, parts or accessories;
	“Veterinary product” means veterinary medicines including biologicals, veterinary medical devices including diagnostics, vitamins and equipment;
	“Wholesale” means a veterinary business which consists of or include wholesaling of veterinary products defined under these Regulations;

## PART II

### REGISTRATION OF PREMISES FOR VETERINARY PRODUCTS

- Premises registration
- Premises to be registered for veterinary products business
- Procedure for registration of premises for business of veterinary products
- GN. 464 of 2015
- Cap. 212
- GN.295 of 2018
- Conditions for registration of premises for wholesale business of veterinary products
4. A person shall not manufacture, supply, store or possess for sale, sell veterinary products except in premises registered with a valid registration.
  - 5(1) For the purposes of these Regulations, the following premises shall be registered by the Authority for veterinary products business:-
    - (a) manufacturing of veterinary products;
    - (b) wholesaling of veterinary products;
    - (c) warehouse as additional storage area for wholesale business; and
    - (d) any other veterinary premises as the Authority may deem fit
  - (2) Notwithstanding with sub-regulation (1) (b) any person intending to deal with both wholesaling and retailing businesses shall be registered under these Regulations.
  6. (1) Application for registration of premises under these Regulations shall be made to the Authority and shall be accompanied by:-
    - (a) Duly filled application form No. F01 and F02 as prescribed in the First Schedule of these Regulations;
    - (b) A sketch drawing of the premises layout;
    - (c) Fee as prescribed in the TFDA Fees and Charges Regulations in force; and
    - (d) In case the applicant is a company, a certificate of incorporation issued under the Companies Act.
  - (2) Subject to the provisions of sub-regulation (1), application for manufacturing premises shall be in accordance with Tanzania Food, Drugs and Cosmetics (Good Manufacturing Practices Enforcement) Regulations in force.
  - (3) Notwithstanding with Sub-regulation (1) (b) construction or renovation shall be after approval of the layout by the Authority.
  7. No wholesale business premises shall be registered unless the following conditions are complied with:-
    - (a) located away from sites or activities that emit obnoxious materials like fumes and contaminants, open sewerage or any other place where safety, quality and efficacy of veterinary products can be compromised;
    - (b) designed such that, it shall have no direct link to building with bar, restaurant, veterinary practice facility, petrol filling station, or in direct link to residential house where the business is carried out;
    - (c) durable, safe and made of permanent building materials, roofed with corrugated iron sheets, concrete slabs or tiles and shall have the floor minimally made up of cement or terrazzo or tiles or any other hard washable surfaces so as to protect veterinary products from potential harmful influences;

- (d) designed and equipped so as to provide protection against rodents, birds and vermins;
  - (e) rooms painted with white washable paint with smooth washable finishing;
  - (f) surroundings are maintained so as to minimize dust and other contamination to enter the building;
  - (g) sufficient lighting, ventilation and optimum temperature to enable operations to be carried out;
  - (h) sufficiently secured to prevent theft and unauthorized entry;
  - (i) has suitable equipment and facilities for proper storage, safety keeping and handling of veterinary products;
  - (j) has a separate secured cabinet with lock and key for keeping controlled drugs;
  - (k) premises for wholesale veterinary business shall have a minimum total area of 40m<sup>2</sup> with not less than 2.5m internal height and demarcated into three (3) rooms for receiving and dispatching, record keeping and storage. The premises must have one main secured entrance;
- Cap. 319
- (l) premises for retail veterinary business shall be in accordance with the Veterinary Act;
  - (n) the name of the proposed business shall be conspicuously displayed on the premises and shall not mislead users of veterinary products or violates any provision of the Act or any other written law of the land; and
- Cap. 319
- (o) Conveyance or van for carriage or transportation of veterinary products shall be pursuant to the Veterinary Act.
- Conditions for registration of warehouses
8. Subject to regulation (7), warehouses connected to the wholesale business shall meet the following conditions:-
- (a) designed and constructed to ensure good storage conditions, sufficient lighting and ventilation;
  - (b) have sufficient capacity to allow for storage of various categories of veterinary products;
  - (c) constructed with durable floor to withstand heavy traffic and loads;
  - (d) provided with well-fitted shelves or pallets; and
  - (e) equipped with temperature and humidity control facilities, monitors and fire extinguishers.
- Inspection of premises
9. (1) Upon receipt of duly filled application forms for premises registration, the Authority shall inspect the premises to verify if all the conditions set under these Regulations have been met.
- (2) When conducting inspection specified in sub regulation (1) the Authority shall use the inspection checklist as prescribed in the Guidelines for Business Licensing, Good Storage and Distribution Practices of Medical and Cosmetic Products in use.
- Issuance of registration
10. (1) The Authority may, if satisfied that the conditions specified in these Regulations are met, register the premises and issue premises registration certificate as prescribed in

certificate and  
business permit

the Second Schedule of these Regulations.

(2) Notwithstanding with sub-regulation (1), the applicant shall not commence any business in the registered premises unless:-

- (a) he possesses a signed proof of an agreement or Power of Attorney with superintendent in direct control of veterinary products; and
- (b) he has obtained a business permit from the Authority as prescribed in the Third Schedule of these Regulations;

Renewal of  
business permit

11. (1) Any business permit issued under these Regulations shall cease to have effect on 30<sup>th</sup> June of every calendar year.

(2) Save for suspension, cancellation, revocation or closure, the business permit shall be renewed on annual basis.

GN.464 of 2015

(3) Renewal of business permits issued under these Regulations shall be made not later than 30<sup>th</sup> July of each calendar year, failure of which shall result into a penalty as prescribed in the Fees and Charges Regulations in force.

Notification of  
changes

12.(1) Any change of the name, ownership, superintendent, location or otherwise of registered premises shall be made to the Authority.

(2) Notwithstanding with sub-regulation (1), change of location shall require a new application.

Voluntary  
cessation of  
business

13. (1) The Authority shall be notified in advance by the owner who wishes to close down the business, to allow for disposal of veterinary products.

(2) Subject to sub-regulation (1), the owner shall return to the Authority the issued registration certificate and business permit in its original format.

(3) Without prejudice to sub-regulation (1), in case the owner wishes to resume the same business, he shall be required to submit a new application as prescribed in these Regulations.

Suspension,  
revocation or  
cancellation of  
business permit

14. (1) The Authority may suspend, revoke or cancel the business permit on one or more of the following grounds-

- (a) that the premises has failed, in any material respect, to comply with the requirements of these Regulations;
- (b) that the storage, sale or distribution of veterinary products cannot be carried out safely;
- (c) that the premises is not under the supervision of an authorized superintendent;
- (d) that the information given by the applicant pursuant to Regulation (5) was false or incomplete in any material aspect; and



- (e) that the premises has been found to stock or distribute unregistered, falsified, government owned or unauthorized veterinary products;
- (2) Subject to sub-regulation (1), before suspending, revoking or cancelling the business permit, the Authority shall serve the notice stating the intention to suspend, revoke or cancel its permits from the date stated in the notice, which shall be not less than 30 days from the date on which the notice is served.
- (3) Where the Authority considers that it is necessary in the interests of animal and public health, the Authority may, by a notice served on the premises, suspend, revoke or cancel its business permit with immediate effect.

### **PART III**

#### **STORAGE, STOCKING AND SELLING OF VETERINARY PRODUCTS**

- |   |  |
|---|--|
| Types of products permitted in wholesale premises | 15. (1) A registered premises for wholesale business shall be permitted to stock, possess, sale, sell or supply the following registered or authorized categories of products:- <ul style="list-style-type: none"> <li>(a) veterinary medicines;</li> <li>(b) veterinary medical devices including diagnostics;</li> <li>(c) vitamins and minerals; and</li> <li>(d) veterinary biological products including vaccines.</li> </ul>   |
| PP Act No.13 of 1997                              | (2) Without prejudice to sub-regulation (1), pesticides may be stocked, sold or supplied in authorized premises subject to conditions specified in the Plant Protection Act.   |
| Seed Act, No.18 of 2003                           | (3) Without prejudice to sub-regulation (1), seed and seed products may be stocked, sold or supplied in authorized premises subject to conditions specified in the Seed Act.   |
| Cap. 378  | (4) Without prejudice to sub-regulation (1), fertilizers may be stocked, sold or supplied in authorized premises subject to conditions specified in the Fertilizers Act.   |
| Cap.180   | (5) Without prejudice to sub-regulation (1), animal feeds may be stocked, sold or supplied in authorized premises subject to conditions specified in the Grazing Land and Animal Feed Resources Act.   |
|   | (6) Without prejudice to sub-regulation (1), agricultural implements may be stocked, sold or supplied in authorized premises.  |
|   | (7) Products specified in sub-regulation 2 – 6, shall be demarcated and shall not compromise the quality and safety of veterinary products.  |
| Storage facilities                                | 16. (1) The storage facility shall meet the following conditions:- <ul style="list-style-type: none"> <li>(a) shall have a confined adequate space for storage of returned, recalled, expired, quarantined, substandard or falsified veterinary products;</li> <li>(b) all veterinary products shall be stored off the floor in well-fitted shelves or pallets;</li> <li>(c) storage conditions shall be maintained and monitored accordingly; and</li> <li>(d) refrigeration for cold chain products shall be monitored using suitable temperature recording devices and power back up system in case of electrical failure.</li> </ul> |

### **PART IV**

## CONDITIONS OF REGISTRATION OF VETERINARY WHOLESALE PREMISES

Supervision and staff of wholesale veterinary premises

17.(1) The wholesale veterinary business shall be under the supervision of a registered pharmacist or veterinarian as superintendent.

(2) Subject to conditions of sub-regulation (1), a certificate of registration of the superintendent shall be conspicuously displayed in the premises.

(3) The following personnel shall conduct their duties in the veterinary premises under the supervision of superintendent;

(a) Pharmaceutical technicians;

(b) Pharmaceutical assistants;

(c) Paraprofessionals; or

(d) Paraprofessional assistants.

Supervision of veterinary manufacturing facilities

18.(1) The veterinary pharmaceutical manufacturing facility shall be under the supervision of a registered pharmacist, chemist, pharmaceutical scientist or technologist, chemical engineer or any other related field as a superintendent.

(2) The veterinary medical devices including diagnostics manufacturing facility shall be under the supervision of a registered biomedical engineer or any other related field as a superintendent.

(3) Without prejudice to sub-regulations (1) and (2), the Authority may permit persons with other qualifications or relevant experience to supervise veterinary manufacturing facilities where it deems fit.

Code of conduct and ethics for superintendent

19.(1) Superintendent shall in the course of discharging his duties observe the code of conduct and ethics prescribed by their professional bodies.

(2) Notwithstanding with sub-regulation (1), superintendent shall observe and maintain the following;

(a) high standards of personnel hygiene;

(b) wear a clean white coat;

(c) not working under the influence of alcohol or illicit drugs;

(d) conduct himself in good and orderly behavior;

(e) be accountable and answerable for all activities conducted therein;

(f) provide services in caring and compassionate manner;

(g) shall not either condone the supply, selling or distribution of veterinary products which are not of good quality or participate in any campaign which encourage their irrational use;

(h) clean premises on regular basis; and

(i) refrain from corrupt practices.

Roles and responsibilities of superintendent

20. The superintendent of any veterinary premises as provided in these Regulations shall have the following roles and responsibilities-

- (a) to provide oversight of the premises in all relevant aspects;
- (b) to be available at the premises at all material times;
- (c) to promote, maintain and improve compliance to legal requirements;
- (d) to ensure personnel and premises cleanliness and tidiness at all times;
- (e) to ensure good conduct of the personnel within the premises;
- (f) to ensure the necessary quality including the correctness, accuracy and completeness of data submitted to the authority;
- (g) to ensure reporting of adverse events and adverse reactions to the Authority;
- (h) to promote rational and safe use of veterinary products;
- (i) to keep records of all batches imported, supplied and distributed to other outlets.
- (j) to timely report all substandard and falsified products to the Authority;
- (k) to maintain records of complaints of customers; and
- (l) to report any misconduct of the veterinary premises to the Authority.
- (m) To keep and maintain a list of registered veterinary products and schedule of medicines.

Owners obligations

21. It shall be the duty of veterinary premises owner to ensure that:-

- (a) the business operations are in conformity with these Regulations; and
- (b) there are no conditions or terms which prohibit the service providers to practice in accordance with provisions of these Regulations.

## PART V

### DISCLOSURE OF INFORMATION AND RECORD KEEPING

Disclosure of information

**22.**-(1) A veterinary premises shall ensure that the information collected for the purposes of these Regulations is held securely.

(2) The information held under sub-regulation (1) shall-

(a) be kept available for the purpose of tracing batches, sales, supplies and any other relevant records; and

(b) not be disclosed except in accordance with one or more of the requirements of sub-regulation (3).

(3) The disclosure requirements of this sub-regulation are-

(a) made in accordance with an order of a court or is otherwise required by law;

(b) made to an inspector appointed by the Director General in accordance with the Act; or

(c) made for the purpose of tracing falsified and substandard products, batches manufactured or products recalled from the market.

(4) Where a disclosure is made to an inspector pursuant to sub-regulation (3)(b), the inspector shall not further disclose the information received unless-

- (a) the disclosure is made in accordance with an order of a court or is otherwise required by law; or
- (b) the disclosure is made to another officer of the Authority where this is necessary for the proper performance of the inspector or officer's duties.
- Data discrepancies **23.**-(1) The superintendent of the veterinary premises shall ensure that they put in place a procedure to ensure that any discrepancies relating to data which are brought to their attention are resolved without delay.
- Record keeping by veterinary premises **24.**-(1) The veterinary premises shall, in relation to the activities specified in these Regulations keep and maintain records for not less than five years.
- (2) The information to be kept, shall include-
- (a) invoices issued;
- (b) import and export permits received;
- (c) delivery notes;
- (d) batches of products supplied;
- (e) records of recalls;
- (e) records of disposal;
- (f) number of each product produced and distributed;
- (g) number of serious adverse events and serious reactions reported; and
- (h) any other document or records as specified in the Tanzania Food, Drugs and Cosmetics (Good Manufacturing Practice Enforcement) Regulations, the Tanzania Food, Drugs and Cosmetics (Registration of Premises, Importation and Exportation of Pharmaceutical Products and Raw Materials) Regulations and the Tanzania Food, Drugs and Cosmetics (Recall, Handling and Disposal of Unfit Medicines and Cosmetics) Regulations in force.
- GN.295 of 2018  
GN.312 of 2015  
GN.313 of 2015
- Records to be kept by the Authority **25.** The Authority shall keep such records of information which it receives from, or relating to, veterinary premises as it considers appropriate and shall, in particular, keep records relating to-
- (a) all registration certificates and permits issued under these Regulations;
- (b) notification of adverse events and adverse reactions by all veterinary premises;
- (c) notification of field safety reports related to medical devices by all veterinary premises;
- (d) notification of quality defects reported by veterinary premises
- (e) inspections or requests for information; and
- (f) any other records as the Authority may deem appropriate.

## PART VI

### GENERAL PROVISIONS

- Objections to suspensions and revocations **26.**-(1) A veterinary premises that-
- (a) objects to any suspension, revocation or cancellation of business permit, or to any notice served; or

- (b) objects to the refusal of the business permit or the imposition of any condition, may notify the Director General of its desire to make written representations to, or be or appear before and be heard by, a person appointed by the Director General for that purpose.
- (2) Any notification of an objection pursuant to sub-regulation (1) shall be made within fourteen days of service on the veterinary premises of the notice to which the notification pursuant to sub-regulation (1) relates.
- (3) Where the Authority receives a notification pursuant to sub-regulation (1), he shall appoint a person to consider the matter.
- (4) The person appointed pursuant to sub - regulation (3) shall determine the procedure to be followed with respect to the consideration of any objection.
- (5) The person appointed pursuant to sub-regulation (3) shall consider any written or oral objections made by the veterinary premises in support of its objection, and shall make a recommendation to the Authority.
- (6) A recommendation made pursuant to sub - regulation (5) shall be made in writing to the Authority, and a copy of it shall be sent to the veterinary premises concerned, or to its nominated representative.
- (7) The Authority shall take into account any recommendation made pursuant to sub - regulation (5).
- (8) Within fourteen days of receipt of any recommendation made pursuant to sub-regulation (5), the Director General shall inform the veterinary premises whether he accepts the recommendation and, if he does not accept it, of the reasons for his decision.
- (9) Where the Director General is notified of an objection pursuant to sub-regulation (1)(a) before the date upon which the suspension, revocation or cancellation or the notice is due to take effect, the suspension, revocation or cancellation of a notice in respect of which the objection is made shall not take effect until:-
  - (a) the person appointed pursuant to sub - regulation (3) has considered the matter in accordance with the provisions of this regulation and made a recommendation; and
  - (b) the Director General has informed the veterinary premises concerned of his decision with regard to the recommendation pursuant to sub - regulation (8).
- (10) Subject to sub-regulation (9), where the Director General is notified of an objection pursuant to sub-regulation (1)(a), within the period specified in sub-regulation (2), to a suspension, revocation or cancellation or other notice which has already taken effect on the date the notification was made, the suspension, revocation or cancellation or notice in respect of which the objection is made shall cease to have effect until:-
  - (a) the person appointed pursuant to sub - regulation (3) has considered the matter in accordance with the provisions of this regulation and made a recommendation; and
  - (b) the Director General has informed the veterinary premises concerned of his decision with regard to the recommendation pursuant to sub - regulation (8).
- (11) The provisions of sub-regulation (10) shall not apply-
  - (a) in relation to a suspension, revocation or cancellation or a notice served, which takes immediate effect in accordance with these Regulations; or

(b) in any other case, where the Director General determines that it is necessary in the interests of public safety for the suspension, revocation or cancellation or notice to take effect on the date originally specified, and serves a notice in writing to that effect on the veterinary premises concerned.

Appeals

**27.**-(1) Notwithstanding with the provisions of regulation 13, any person aggrieved by a decision of the Authority may, within sixty days appeal in writing to the Minister.

(2) The appellant shall copy a notice of the appeal to the Authority who shall within fourteen days submit a written response to the Minister and copy the appellant.

(3) Where the Minister is of the opinion that a case has been made, he may summon parties for additional information or make a decision to allow or dismiss the appeal.

Offences and penalties

**28.** Any person who contravenes or fails to comply with these Regulations or directly or indirectly aids any other person to do what is prohibited under these Regulations shall be guilty of an offence and on conviction, shall be liable to the penalty prescribed by the Act.

Compounding of offences

**29.**-(1) The Director General, Inspector or any other authorized person may, subject to and in accordance with the provisions of these Regulations, if he is satisfied that a person has committed an offence against these Regulations, compound such offence by accepting from such person a sum of money in respect of which the offence has been committed.

(2) The sum of money payable under sub-regulation (1) shall not exceed five times the maximum amount of the fine prescribed as being payable in respect of such offence.

(3) The Power conferred by this section shall be exercised where a person admits that he has committed an offence and agrees in writing in the prescribed form to the offence being dealt with under this regulation.

(4) The Director General or officer exercising powers under this regulation shall give to the person from whom he receives any sum of money under subsection (2) a receipt which shall be in a prescribed form.

(5) Any sum of money received under this regulation shall be paid into the Authority.

(6) If any proceedings are brought against any person for an offence against these Regulations, it shall be a good defence if such person proves that the offence with which he is charged has been compounded under this regulation.”

## SCHEDULES

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### FIRST SCHEDULE

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APPLICATION FORM FOR WHOLESALE VETERINARY PREMISES

FORM No.F01

 <p><b>TFDA</b> Tanzania Food &amp; Drugs Authority</p>	<p>APPLICATION FORM FOR REGISTRATION OF PREMISES AND BUSINESS PERMIT</p>	<p>TFDA/DMC/MCIE/F/029  Rev #: 01</p>
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(Made under Regulation 6)

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

**SECTION A: APPLICANT INFORMATION**

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

1. Name of applicant.....

2. Postal address..... Tel, No..... Fax..... Email.....

3. In case of

(a) \*Corporate body; name of Directors.....

(b) \*Partnership; name of Partners.....

(c) Joint venture; name of Consortium.....

4. Situated at/lying between Plot /Vessel/ Truck No  
.....Street/Village/Ward.....District/Municipality/City.....  
.....

5. Premises to be registered for the business of.....

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

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

**SECTION B: DECLARATION BY APPLICANT**

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

**N.B. False declaration constitutes an offence.**

Date.....

Signed.....

**Applicant**

*\* Attach Certificate of Incorporation*

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**SECOND SCHEDULE**

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WHOLESALE VETERINARY PREMISES REGISTRATION CERTIFICATE

*(Made under Regulation 10)*



TANZANIA FOOD AND DRUGS AUTHORITY



PREMISES REGISTRATION CERTIFICATE

(Made under Section 21(3) of the Tanzania Food, Drugs and Cosmetics Act, Cap 219)

Premises Registration Number:

This is to certify that the premises owned by M/S ..... of P.O. Box ..... located at ..... in ..... District/Municipal ..... region has been registered to .....

Subject to the following conditions:-

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

Issued on:

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.....

ACTING DIRECTOR GENERAL

THIRD SCHEDULE

PERMIT FOR WHOLESALE VETERINARY BUSINESS
(Made under Regulation 10)

TANZANIA FOOD AND DRUGS AUTHORITY



**BUSINESS PERMIT**

*(Made under Section 21(3) of the Tanzania Food, Drugs and Cosmetics Act, Cap 219)*

**Business Permit No:**

Permit is hereby granted to M/S..... of P.O. Box ..... to operate a ..... at the premises with Registration No.....situated at ..... in ..... District/Municipality in ..... region.

This Permit is valid until .....

Issued on

Fees Paid: ..... Receipt No: .....

.....  
.....

**ACTING DIRECTOR GENERAL**

**Note:**

1. This Permit does not authorize the holder to operate business in unregistered premises or during the period of suspension, revocation or cancellation of registration of the premises in respect of which it was issued.
2. This Permit is not transferable without approval of the Authority.

**Dodoma**  
....., **2018**

**UMMY MWALIMU**  
*Minister for Health, community Development, Gender,  
Elderly and Children*