

SUBSIDIARY LEGISLATION

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THE ANIMAL DISEASES ACT (CAP. 156)

REGULATIONS

(Made under section 65)

THE ANIMAL DISEASES (VACCINES AND VACCINATION) REGULATIONS, 2020

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GN. No. 180 (contd.)

THE ANIMAL DISEASES ACT,
(CAP. 156)

REGULATIONS

(Made under section 65)

THE ANIMAL DISEASES (VACCINES AND VACCINATION) REGULATIONS, 2020

PART I
PRELIMINARY PROVISIONS

- | | |
|----------------|--|
| Citation | 1. These Regulations may be cited as the Animal Diseases (Vaccine and Vaccination) Regulations, 2020. |
| Interpretation | 2. In these Regulations, unless the context otherwise requires- |
| Cap. 156 | “Act” means Animal Diseases Act;
“buffer zone” means an area established within and along the border of an infected area using measures based on the epidemiology of the disease under consideration to prevent the spread of the causative agent;
“Director” means the Director of Veterinary Services under the Ministry responsible for livestock;
“District Veterinary Officer” means a veterinarian in charge in a district;
“flock” means group of sheep, goat or poultry kept together;
“herd” means group of cattle kept together;
“inspector” means an inspector appointed under section 4 of the Act;
“livestock” means any domesticated animal and includes cattle, sheep, goat, pig, horse, camel, water buffalo, dog, cat, game, donkey and chicken; |

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“non-invasive vaccines” means any vaccine administered by any route other than through injection;

“owner” includes any person having any right, title or interest in an animal or having any animal in his possession, custody or control and the owner in respect of a dead animal, means owner of the dead animal or person who is in possession or control of it;

“route” means the path by which a vaccine is taken into the body;

“strategic diseases” means diseases listed by the Director for compulsory control by vaccination;

“vaccine” means a remedy administered to an animal to produce active or passive immunity, to diagnose the state of immunity or to help the immune system to develop protection from diseases;

“vaccination” means the administration of vaccine to an animal;

“vaccination completeness” means percentage of target areas vaccinated around campaign;

“vaccination coverage” means percentage of target population vaccinated;

“vaccinator” means a person authorised to administer vaccine to the animal body by either injection or any other route;

“vaccine handlers” means a person or institution responsible for storage, transportation and delivery of vaccines;

“Veterinary Council of Tanzania” means the Council established under section 3 of the Veterinary Act.

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Objectives

3. The objectives of these Regulations are-
- (a) ensuring efficient production of vaccines in the country using good manufacturing practises;
 - (b) ensuring efficient importation of good quality vaccine from Good Manufacturing Practice (GMP) certified factories;

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- (c) ensuring efficient and effective vaccination of animals against diseases;
- (d) ensuring the use of quality veterinary vaccines;
- (e) ensuring vaccines are delivered to vaccine user at affordable price;
- (f) ensuring acquisition and distribution of vaccines through credible distribution channel;
- (g) ensuring safe disposal of unused vaccine and waste materials.

PART II

GENERAL VACCINE AND VACCINATION MANAGEMENT

Vaccine
management

4. The Director shall-

- (a) be responsible for monitoring and controlling the manufacture of vaccines in the country;
- (b) approve vaccines to be manufactured in the country for biosecurity reasons;
- (c) conduct field trials for new vaccines before they are made available for use in the country;
- (d) authorise use of manufactured vaccines after passing the trial.

Establishment
of Vaccine
Advisory
Committee

5.-(1) For the purpose of vaccine regulation, there shall be a Vaccine Advisory Committee established by the Minister.

(2) The Vaccine Advisory Committee shall consist of the following members-

- (a) a person with business knowledge;
- (b) a microbiologist;
- (c) a representative from the Authority responsible for regulating procurement;
- (d) a Law Officer from the Office of the Attorney General;
- (e) the Director of Veterinary Services;
- (f) a representative from the Tanzania Medicine and Drugs Authority;
- (g) a representative from an association of vaccines

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	importers; and (h) a representative from an association of livestock keepers. (3) The Registrar of the Veterinary Council of Tanzania shall the Chairperson of the Committee and Director of Veterinary Services shall be Secretary to the Committee.
Functions of Vaccine Advisory committee	6.-(1) The functions of the Vaccine Advisory Committee shall be- (a) advising the Director of Veterinary Services on all matters concerning manufacturing, importation ,distribution of vaccines and vaccination of strategic diseases; (b) advising on pricing and monitor bulk procurement of strategic vaccines; (c) prescribing the type and volume of vaccines to be imported into the country. (2) The Vaccine Advisory Committee shall regulate its own procedures including the number of its meetings. (3) Members of the Advisory committee shall serve for a term of three years which may be renewed once.
Importation and distribution of vaccine	7.-(1) The Director shall regulate importation and distribution of vaccines by- (a) authorising the use of vaccines; (b) keeping and maintaining a list of importers, manufacturers and distributors of vaccines annually; (c) determining importers, distributors and distribution and delivery channels of vaccines depending on the need or circumstances. (2) Without prejudice to subregulation (1), importers, manufacturers and distributors shall adhere to regulations 13 and 14.
Delivery and use of veterinary vaccines	8.-(1) The Director shall regulate and authorise the delivery and use of veterinary vaccines. (2) Vaccination using invasive and non invasive

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methods shall be carried out by registered veterinarian, enrolled and enlisted paraprofessional under the supervision of a District Veterinary Officer.

(3) Notwithstanding subregulation (2), the owner may be allowed to administer non-invasive vaccines under manufacturer's instructions.

Vaccination for
strategic
diseases

9.-(1) For the purpose of disease control, livestock shall be vaccinated against strategic diseases listed in the First Schedule to these Regulations.

(2) The Director shall update the list of strategic diseases where deemed necessary.

(3) The District Veterinary Officer shall prescribe the station, date and time for the specified vaccination programme.

(4) A livestock owner shall present all animals eligible for vaccination to the vaccination area and ensure that they have been vaccinated.

(5) Livestock shall be vaccinated against strategic diseases using approved and authorised vaccines which may be manufactured locally or imported.

(6) Imported vaccines for strategic diseases shall be procured through bulk procurement.

(7) Vaccination for strategic diseases shall be compulsory.

(8) Unless otherwise stated, costs for vaccination shall be borne by the owner or caretaker of livestock.

Requirement
for vaccination
of animals

10. Every owner of livestock shall-

- (a) have their animals timely vaccinated against strategic diseases;
- (b) adhere to vaccination calendar for the livestock;
- (c) retain the original copy of the animal vaccination certificate as prescribed in the Second Schedule;
- (d) maintain records of vaccination of the herd or flock in the format prescribed in the Third Schedule.

Responsibility
of vaccinator or

11.-(1) The vaccinator shall-

- (a) receive vaccines from authorised distributors;

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farm owner

- (b) maintain vaccines at recommended temperature;
- (c) administer the right dosage, route and body site according to vaccine manufacturer's instruction;
- (d) keep and maintain vaccination records;
- (e) report vaccination records to the District Veterinary Officer.

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(2) Any person, being a registered veterinarian, veterinary specialist, para professional or professional assistant, who contravenes subregulation (1) shall be in breach of professional conducts provided under the Veterinary Act.

Vaccination
calendar

12.-(1) The Director shall provide a calendar for routine vaccination against strategic diseases as prescribed in the Fourth Schedule.

(2) In the event of disease outbreak, the Director shall order emergency vaccination at buffer zone.

(3) In the event of export requirement, the Director shall order vaccination of animals for export and indicate duration of stay before export.

Vaccine quality
management

13.-(1) The Director shall ensure that-

- (a) vaccines imported into the country have a minimum of six months before the expiry date at the time of delivery, save in the event of emergency or new disease outbreak, the vaccine may have a minimum of two months before the expiry date at the time of delivery;
- (b) all imported and local manufactured vaccines are registered by the Director after submission of competent laboratory certification for vaccine;
- (c) vaccines are stored in temperature recommended by the manufacturer at all times until delivery;
- (d) delivery of the vaccine complies with the manufacturer's instructions.

(2) Notwithstanding subregulation (1)(d), a vaccinator shall dilute powdered vaccine or pellet according to manufacturer's recommended diluents.

(3) The Director may, at any stage, take samples of

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vaccine for quality testing.

Vaccine pricing

14. In order to ensure fair price of vaccine delivery-
- (a) local manufacturers shall indicate and update on regular basis the gate price of vaccines per dose;
 - (b) the Director shall, after being advised by the Vaccine Advisory Committee, set indicative prices for vaccines;
 - (c) the Director shall determine the volume of vaccines to be imported and if bulk procurement is preferred.

PART III

HANDLING AND TRANSPORTATION OF VETERINARY VACCINES

Handling and
transportation
of vaccines

- 15.-(1) Vaccines shall be stored and transported using equipment with the temperature specified by manufacturers.
- (2) Vaccine handlers shall be responsible for maintenance of temperatures specified by the manufacturers.
- (3) Vaccine manufacturers shall provide temperature indicators.
- (4) Vaccines shall be transported in such a manner that-
- (a) cold chain is maintained;
 - (b) breakage of vaccine containers is avoided.

Vaccine storage

16. Vaccines shall be stored in following manner-
- (a) bulk storage shall be done in walk-in cold rooms (WIC) and walk-in freezer rooms (WIF) with temperature controlled supply chain;
 - (b) vaccines shall only be stored in a specialised refrigerator known as 'vaccine refrigerator' that-
 - (i) has specific designed refrigeration system that meets vaccines manufacturer's recommendations;
 - (ii) has micro compressor controls that ensure correct temperature throughout the chamber;

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- (iii) allows rapid temperature recovery following door openings;
- (iv) maintains temperature for a minimum of twenty four hours after power failure;
- (v) ensures alternative source of power in case of power failure;
- (c) notwithstanding paragraph (b), vaccines shall be stored in a freezer or liquid nitrogen as per manufacturer's instruction.
- (d) storage of vaccines in the fields shall be done using cool boxes made from insulated containers lined with conditioned ice packs to keep vaccines cool but not frozen.

Disposal of waste materials

17.-(1) Used vaccine containers, syringes, needles, gloves, biological wastes and any other materials shall be disposed in accordance with laws governing disposal of waste materials.

(2) The cost of decontamination shall be borne by the vaccinator or farm owner.

PART IV

MONITORING OF VACCINES AND VACCINATION

Vaccination coverage and completeness

18.-(1) Vaccination coverage shall be at least 70% of the target population and completeness shall be 100% of the targeted area.

(2) The Director shall monitor-

- (a) the completeness of vaccination.
- (b) the effectiveness of vaccination by monitoring the level of immunity attained after vaccination.

(3) Owners of vaccinated livestock shall allow sampling for monitoring purposes.

Certification and recording of vaccinated animals

19.-(1) The owner of vaccinated pets shall be issued a certificate upon vaccination.

(2) The owner of a vaccinated pet shall provide vaccination certificate as proof of vaccination upon request by an inspector.

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(3) The owner of vaccinated livestock shall-

- (a) keep records of all vaccinations;
- (b) provide vaccination records as proof upon request by an inspector.

(4) Vaccinators shall submit a written vaccination report to the District Veterinary Officer within seven days after vaccination.

(5) A District Veterinary Officer shall maintain record of vaccination within the area of his jurisdiction.

PART V

MISCELLANEOUS PROVISIONS

Offences and penalties

20. Any person who contravenes any of the provisions of these Regulations commits an offence and shall, upon conviction, be liable to a fine of not less than five hundred thousand shillings but not exceeding ten million shillings or imprisonment for a term of not less than six months but not exceeding twelve months or to both.

Compounding of offences

21.-(1) Pursuant to the provisions of section 62A of the Act, where a person admits commission of an offence under these Regulations, the Director or an authorised officer may issue a compounding order and accept a sum of money not exceeding five million shillings.

(2) The following offences may be compounded under these Regulations-

- (a) manufacture of counterfeit vaccines;
- (b) importation of counterfeit vaccines;
- (c) distribution of counterfeit vaccines;
- (d) operating a manufacturing facility without a permit;
- (e) failure to take livestock for vaccination.

(3) A person who admits commission of an offence under subregulation (1) shall fill the Compounding Form set out in the Fifth Schedule and submit it to the Director or authorised officer.

(4) Notwithstanding subregulation (1), where a person admits commission of the offence under subregulation (2)(e),

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the compounding officer shall order payment of the amount set out in the Sixth Schedule.

FIRST SCHEDULE

(Made under regulation 9 (1))

LIST OF STRATEGIC DISEASES FOR COMPULSORY VACCINATION

NO	DISEASE	SPECIES
1.	Contagious Bovine Pleural Pneumonia (CBPP)	Cattle
2.	Contagious Caprine Pleural Pneumonia (CCPP)	Goats
3.	Peste Des Petits ruminants (PPR)	Sheep and goats
4.	Anthrax	Cattle, sheep, goats, pigs, donkeys
5.	Newcastle Disease (ND)	Poultry.
6.	Rabies	Dogs and cats
7.	East Coast Fever (ECF)	Cattle
8.	Rift Valley Fever (RVF)	Cattle, sheep, goats and water buffalo
9.	Brucellosis	Cattle, sheep and goats
10.	Foot and Mouth Disease (FMD)	Cattle, sheep, goats, pigs
11.	Lumpy Skin Disease (LSD)	Cattle
12.	Mareks	Exotic Chicken
13.	Infectious bursal disease (IBD) –Gumboro	Poultry

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SECOND SCHEDULE

(Made under regulation 10(c))

ANIMAL VACCINATION CERTIFICATE

WIZARA YA MIFUGO NA UVUVI (Ministry of Livestock and Fisheries) IDARA YA HUDUMA ZA MIFUGO (Directorate of Veterinary Services)  KADI YA CHANJO (Vaccination card) (MBWA NA PAKA) (Dogs and Cats)	Tarehe ya chanjo (Date of vaccination)	Aina ya chanjo (Type of vaccine)	Batch No (Toleo)	Jina na Saini (Name and Signature).	Tarehe ya chanjo nyingine (Date of next vaccination)

Jina la mwenye mbwa/paka (Owner's name)		Simu (Tel)		
Anuani/kijiji _____ (Address Village)				
Jina la mbwa/paka (Pet name)	jinsi me/ke (Sex M/F)	umri wakati wa chanjo ya kwanza (Age at first vaccination)		
Aina _____ (Breed)	Rangi _____ (colour)			

Tarehe ya chanjo (Date of vaccination)	Aina ya chanjo (Type of vaccine)	Batch No (Toleo)	Jina na Saini (Name and Signature)	Tarehe ya chanjo nyingine (Date of next vaccination)

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THIRD SCHEDULE

(Made under regulation 10(d))

HERD/FLOCK VACCINATION RECORD (KUMBUKUMBU YA CHANJO KWA KUNDI LA MIFUGO)

Jina la mfugaji/Name of Farmer

Anuani/Address.....

Barua pepe/Email..... Simu/Phone.....

Kijiji/Village.....Mtaa/Street..... Wilaya/District.....

Ijazwe na mtoa chanjo/To be filled by vaccinator

Na.	Aina ya chanjo (type of vaccine)	Toleo (Batch No)	Tarehe chanjo inapotolewa (Vaccination date)	Tarehe ya kurudia chanjo (next vaccination)	Tarehe ya mwisho wa chanjo kutumika (expiry date)	Aina ya Mifugo (Species)	Idadi ya mifugo aliyonayo mfugaji (Herd/flock size)	Idadi ya mifugo iliyochanjwa (No. of vaccinated animals)	Jina, Saini na namba ya simu ya mtoa chanjo)(Name, signature and tel. no. of vaccinator)

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FOURTH SCHEDULE

(Made under regulation 12(1))

CALENDAR FOR VACCINATION

NO	DISEASE	TIME OF THE YEAR
1.	Contagious Bovine Pleural Pneumonia (CBPP) (Homa ya Mapafu ya Ng'ombe)	July and October
2.	Contagious Caprine pleural pneumonia (CCPP) (Homa ya Mapafu ya Mbuzi)	July and October
3.	Peste Des Petits Ruminants (PPR) (Sotoka ya Mbuzi na Kondoo)	April to June
4.	Anthrax (Kimeta)	August to October
5.	Newcastle Disease (ND) (Mondo/Kideri)	January, May, September
6.	Rabies (Kichaa cha Mbwa)	September
7.	East Coast Fever (ECF) (Ndigana Kali)	January to December
8.	Rift Valley Fever (RVF) (Homa ya Bonde la Ufa)	Depending on weather forecast Inategemea na utabiri wa hali ya hewa
9.	Brucellosis (Ugonjwa wa Kutupa Mimba)	January to December
10.	Foot and Mouth Disease (FMD) (Ugonjwa wa Miguu na Midomo)	February, June and October
11.	Lumpy Skin Disease (LSD) (Mapele Ngozi)	October to December

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FIFTH SCHEDULE

(Made under regulation 21(3))

COMPOUNDING FORM

(To be filled in triplicate)

1. Particulars of person whose offence is being compounded:

Full name

Residential address

Place/village District Region

Time of arrest.....Date

Animal Species

Condition of Animal

2. Declaration of person whose offence is being compounded:

I (*three names*)..... resident of

Age (*years*) sex admit that I have committed an offence of
(*tick which is appropriate*):

- (i) Manufacturing of counterfeit vaccines;
- (ii) Distribution of counterfeit vaccines;
- (iii) Importation of counterfeit vaccines;
- (iv) Failure to vaccinate Livestock,

and accept to pay the amount of Tshs. as penalty for commission
of the offence.

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Signature of a person whose offence has been compounded Date.....

Full name of witness (if any)

Residential address

Signature of witness

3. For Official use

Amount of money paid for the compounded offence

Tshs.....For.....

Exchequer Receipt Voucher (ERV) No.....

Date.....

Full name(s) and signature(s) of Authorized Officers/Enforcement Officer/ Inspector
compounding an offence

1. Name:

Signature: Date

2. Name:

Signature: Date

3. Name:

Signature:Date

.....

Official Stamp

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SIXTH SCHEDULE

(Made under regulation 21(4))

AMOUNT TO BE PAID AS PENALTY FOR FAILURE TO VACCINATE LIVESTOCK

S/N	ANIMAL SPECIES	AMOUNT PER HEAD IN TSHS
1	Failure to vaccinate cattle	5,000
2	Failure to vaccinate goat	2,000
3	Failure to vaccinate sheep	2,000
4	Failure to vaccinate dog	20,000
5	Failure to vaccinate cat	5,000
6	Failure to vaccinate pig	3,000
7	Failure to vaccinate horse	20,000
8	Failure to vaccinate camel	5,000
9	Failure to vaccinate water buffalo	5,000
10	Failure to vaccinate donkey	5,000
11	Failure to vaccinate chicken	200

Dodoma,
20th February, 2020

LUHAGA JOELSON MPINA,
Minister for Livestock and Fisheries