

THE VETERINARY MEDICINES DIRECTORATE

(VMD C)

About VMD



Ministry of Agriculture, Livestock, Fisheries & Co-operatives



State Department for Livestock



VMD / VMDC



Physical Location- PCPB Plaza Loresho

Establishing legislation

- Veterinary Surgeons & Veterinary Para-professionals Act Section 39 (2)
- The Veterinary Surgeons & Veterinary Paraprofessional (Veterinary Medicines Directorate) Regulations, 2015
- Regulatory agency ensures compliance with the Regulations

Governance

- Governing body: Council appointed under the Regulations
 - Council Committees
- Day to day Management under CEO appointed by the Council
 - Departments
 - Sections
 - Units

VISION

World Class Regulatory Agency for Veterinary Medicines

MISSION

Safeguard Animal and Public health & environment and promote animal welfare by assuring safety, quality, effectiveness of veterinary medicines

MANDATE

Regulate the Manufacture, Importation, Exportation, Registration, Distribution, Prescription and Dispensing of veterinary medicines and practice of veterinary Pharmacy

Classes of Veterinary Medicines

A). VETERINARY
PHARMACEUTICALS

C)) BIOLOGICALS

E). ALTERNATIVE
MEDICINES

B) NUTRIENTS
(PRE-MIXES)

D). VETERINARY
PESTICIDES

EQUIPMENTS AND
MATERIALS OF
VETERINARY
RELEVANCE

Categories of Veterinary Medicines

Second Schedule

Category I: Prescription Only Medicines Vet Surgeon (POM V)

Category IA: Controlled Veterinary Medicines

Category IB: Other POMs

Category II: Prescription Only Medicines- VT (Veterinary Surgeon, Pharmacist, Veterinary Technologist)

Categories of Veterinary Medicines

**Category III: Authorised Veterinary Medicines
General Sales List (AVM-GSL)**

**Vet surgeons and all categories of
paraprofessionals**

**Category IV: Alternative Veterinary Medicines
General Sales List (Alt VM-GSL)-**

Categories of Veterinary Pharmacies

1. Manufacturers

2. Wholesalers

3. Retailers

Functions of VMD

The Functions of the Directorate: Regulation 6;

- Formulate & Enforce quality assurance standards in the manufacture, distribution and use of VMs ;
- In consultation with DVS regulate the use of VMs for the treatment of animals under the Animal Diseases Act.;
- Consider applications for approval for market authorization of VMs;
- Collaborate with the KVB in regulating training in the management of VMs;
- Inspect and approve premises conducting Manufacture, sale or supply of VMs;

Functions Cont....

- Appoint and Gazette veterinary medicine inspectors & Establish SOPs for the Inspectors;
- Regulate Veterinary Pharmacy Practices;
- Ensure that the promotion and marketing of VMs is in accordance with the approved product information
- Categorize VMs and the qualification of persons authorized to trade in each category and review the categories every five years;
- Regulate clinical and non-clinical trials of veterinary medicines by individuals and institutions;

Functions Cont....

- Regulate the Manufacture, Importation, Exportation, Handling, Advertisement, Labeling, Sale and Disposal of VMs
- Register all VMs: Manufactured, Imported or Exported from the country;
- Monitor the market for and take measures necessary for the elimination of trade in illegal VMs
- Establish systems of pharmaco-vigilance and conduct pharmaco-vigilance of VMs;
- Enforce good manufacturing practice for veterinary medicines as approved by the Council;

Functions Cont..

- Enforce GMP for VMs as approved by the Council;
- Consider, grant, issue or revoke authorizations and certificates in accordance with these Regulations; publish,
- On an annual basis, on 31st March, Publish a notice in the Kenya Gazette inviting the public to note and inspect the register of VMs and approved veterinary pharmacy practices within such period and at such place as may be specified in the notice;

Fees

Regulation 7 gives the Council all the power necessary or expedient for the effective discharge of its functions under these Regulations and any other law:

7(d) Levy and charges for its services as provided in the Regulations:

Fifth Schedule

Offences



A person commits an offence if that person contravenes any provisions of the Regulations

Internal:

11(4). Conflict of interest that is not declared

55(b). Wilfully obtaining or seeking to obtain confidential information to which one is not entitled

External

21(7). A person in executive authority of a manufacturing company which manufactures without a licence commits an offence

54. If an institution commits an offence under the Regulations, the officer, director or agent of corporation who directed, authorised, assented, acquiescence or participated in the commission of the offence shall be considered to have committed the offence

Penalties

Fine not exceeding one hundred thousand shillings or to imprisonment for a term not exceeding twelve months or both

Our Commitment/Your Obligation

VMD committed to implement the provisions of the Regulations uniformly to ensure level playing field for all

Vet Pharma to conduct Legal and clean businesses - Regulations and other Laws

THANK YOU