

**THE VETERINARY SURGEONS AND VETERINARY
PARAPROFESSIONALS ACT
(CAP 366)**

IN EXERCISE of the powers conferred by section 45 of the Veterinary Surgeons and Veterinary Paraprofessionals Act, Cap. 366, the Cabinet Secretary makes the following regulations: —

**THE VETERINARY SURGEONS AND VETERINARY
PARAPROFESSIONALS (THE VETERINARY MEDICINES
DIRECTORATE) REGULATIONS, 2022
PART I—PRELIMINARY**

<p>1. These Regulations may be cited as the Veterinary Surgeons and Veterinary Paraprofessionals (Veterinary Medicines Directorate) Regulations, 2022.</p>	<p>Citations</p>
<p>2. In these Regulations, unless the context otherwise requires— “accredited laboratory” means a laboratory recognized as an accredited laboratory by the Directorate; “Act” means the Veterinary Surgeons and Veterinary Paraprofessionals Act Cap. 366” “advertisement” means any written or visual notice, circular, label, or wrapper, or other descriptive matter, verbal statement or reference appearing in any newspaper, television, film or mass media or brought to the attention of the public in any other form, which is intended to promote the sale of a veterinary medicine; “alternative medicine” means the unrefined plant, animal and mineral substances used in animal treatments; “Cabinet Secretary” means the Cabinet Secretary responsible for matters relating to veterinary medicines; “Chief Executive Officer” means the Chief Executive Officer of the Directorate appointed under regulation 13; “Controlled Veterinary Medicine” means a veterinary medicine specified in the Fourth Schedule as a Category I or Category II of veterinary medicines; “Conventional medicines” means the regular and standardized veterinary medicines; “Council” means the Council of the Directorate appointed under regulation 8 (1); “County Director” means a County Director of Veterinary Services in a county government; “Crude drug” means an unrefined medicine of biological or mineral origin; “Designated Laboratory” means a laboratory designated by the Directorate for its purpose under these Regulations; “Director” means the Director of Veterinary Services as defined in the Act; “Directorate” means the Veterinary Medicines Directorate established under regulation 5 and as envisaged under section 39 (2) (a) of the Act; “dispense” means the sale or supply of a veterinary medicine by a veterinary surgeon or other person authorised in accordance with these Regulations; “General Sale List Medicine” means a veterinary medicine which has been deemed safer than prescription medicines when taken correctly;</p>	<p>Interpretations</p>

<p>“Good Manufacturing Practices” means good manufacturing practices recognized by the World Health Organization”</p> <p>“inspector” means a person appointed as an inspector under regulation 19 (1);</p> <p>“manufacture” means any stage in the manufacturing of a veterinary medicine until the finished product is ready for sale or use in its final form as specified in the market authorization, and includes re-packaging, repacking or labeling of a veterinary medicine in an authorized facility but does not include the breaking open of the package of a veterinary medicine by retailers;</p> <p>“market authorization” means registration of a veterinary medicine by the Directorate and the issuance of a registration certificate under regulation 23;</p> <p>“orphan veterinary medicine” means a veterinary medicine that is not economical to trade in but is required for specific veterinary use;</p> <p>“pharmaco-vigilance” means the routine surveys, data collection and management carried out in the veterinary medicines market to safeguard general animal, human, environmental health, and trade;</p> <p>“Premises” means premises which is recognized by the Directorate, through registration for purposes of manufacturing, formulating, packaging, selling or storing veterinary medicines;</p> <p>“quality assurance standards” means the standards which the Cabinet Secretary, on the advice of the Council, shall recognize through the Gazette as a quality assurance standard for the purposes of these Regulations;</p> <p>“register” means a register maintained by the Directorate containing the details in Form C, D and J in the Third Schedule of these Regulations</p> <p>“Registration committee” means the Veterinary Medicines Registration Committee established under regulation 33;</p> <p>“Retention” maintenance of registered products in the register;</p> <p>“retailer” means a veterinary pharmacy registered by the Directorate for the sale of veterinary medicines to the end users;</p> <p>“veterinary pesticide” means a veterinary medicine used as a pest control product on animals or the animals’ environment;</p> <p>“veterinary pharmaceutical” means a chemical substance formulated or compounded as a single active ingredient or in any combination of the chemical substances, for veterinary use;</p> <p>“veterinary pharmacist” means a person carrying out the business of a veterinary pharmacy</p> <p>“veterinary pharmacy” means a business carried out by a veterinary surgeon, a veterinary para-professional or any other person authorized by the Directorate to stock, dispense or distribute veterinary medicines;</p> <p>“wholesaler” means a manufacturer or veterinary pharmacy approved by the Directorate to trade in bulk in the supply of veterinary medicines to wholesalers or retailers</p>	
<p>3. The objects and purpose of these Regulations is to—</p> <p>(a) establish the Veterinary Medicines Directorate;</p> <p>(b) regulate the manufacture, importation, exportation, registration, distribution, prescription and dispensing of veterinary medicines;</p> <p>(c) regulate the practice of veterinary pharmacy in Kenya.</p>	<p>Objects and purpose of the Regulations</p>
<p>4. These Regulations shall apply to all conventional and alternative veterinary medicines that are not exempted under regulation 64.</p>	<p>Application</p>

PART II — THE VETERINARY MEDICINES DIRECTORATE	
<p>5. (1) There is hereby established a Directorate to be known as the Veterinary Medicines Directorate;</p> <p>(2) The Directorate shall be a body corporate with perpetual succession and a common seal and shall in its corporate name be capable of—</p> <p>(a) suing and being sued;</p> <p>(b) taking, purchasing, or otherwise acquiring, holding, charging or disposing of movable and immovable property;</p> <p>(c) borrowing and lending money; and</p> <p>(d) doing all such other things or acts as may lawfully be done by a body corporate.</p>	<p>Establishment of the Directorate</p>
<p>6. The functions of the Directorate are to—</p> <p>(a) Formulate and enforce quality assurance standards in the manufacture, distribution, and use of veterinary medicines to safeguard human and animal health and the environment;</p> <p>(b) Regulate the use of veterinary medicine for the treatment of animals under the Animal Diseases Act and any other written Law provided the Director may prohibit the use of any Veterinary medicines for treatment of Animal diseases;</p> <p>(c) collaborate with the Kenya Veterinary Board in regulating training in the management of veterinary medicines;</p> <p>(d) inspect and approve premises in which the manufacture of veterinary medicines is conducted;</p> <p>(e) appoint and gazette veterinary medicine inspectors;</p> <p>(f) Register and license all manufacturers, Wholesalers and retailers of veterinary medicines;</p> <p>(g) regulate veterinary pharmacy;</p> <p>(h) categorize veterinary medicines and the qualification of persons authorized to trade in each category and review the categories from time to time;</p> <p>(i) regulate clinical and non-clinical trials of veterinary medicines by individuals and institutions to be involved in the trials;</p> <p>(j) regulate the manufacture, importation, exportation, handling, advertisement, labeling, sale and disposal of veterinary medicines;</p> <p>(k) register all veterinary medicines manufactured or imported for use in the country or exported from the country;</p> <p>(l) monitor the market and take measures necessary for the elimination of trade in illegal and counterfeit veterinary medicines;</p> <p>(m) establish systems of pharmaco-vigilance and conduct pharmaco-vigilance of veterinary medicines;</p> <p>(n) undertake any other functions necessary for the effective carrying out of its mandate under these regulations or the Act.</p>	<p>Functions of the Directorate</p>
<p>7. The Directorate shall have all the power necessary or expedient for the effective discharge of its functions under these Regulations and in particular the power to—</p> <p>(a) control, supervise and manage its assets and liabilities;</p> <p>(b) determine the provision to be made for capital and recurrent expenditure and for the reserves of the Directorate;</p> <p>(c) seek and receive any grants or donations and make legitimate disbursements from such grants and donations for its purposes;</p> <p>(d) levy fees and charges for its services as provided in these Regulations;</p> <p>(e) enter into association with other bodies within or outside Kenya which it considers desirable or appropriate;</p>	<p>Powers of the Directorate</p>

<p>(f) invest funds of the Directorate not immediately required for its purposes;</p> <p>(g) establish and support investment and trust funds for the benefit of its employees or ex-employees or dependants of such persons, to grant pension, benefits and allowances and to make such payments towards insurance as required under the relevant laws;</p> <p>(h) open and operate such accounts as are necessary for the funds of the Directorate;</p> <p>(i) enter into contracts;</p> <p>(j) undertake any activity necessary for the fulfillment of any of its functions.</p>	
<p>8. (1) The management of the Directorate shall vest in a Council which shall consist of—</p> <p>(a) A chairperson who shall be appointed by the President;</p> <p>(b) the Director of Veterinary Services;</p> <p>(c) the Principal Secretary for the time being responsible for Finance;</p> <p>(d) the Principal Secretary for the time being responsible for veterinary medicines;</p> <p>(e) two veterinary surgeons one from the pharmaceutical industry and one from an institution of higher learning training in pharmacology;</p> <p>(f) one veterinary technologist from the veterinary pharmaceutical industry</p> <p>(g) One animal producer who is not a veterinary surgeon or a veterinary para professional;</p> <p>(h) The Chairman of the County Veterinary Services Committee;</p> <p>(i) the Chief Executive Officer of the Directorate who shall be the Secretary to the Council and shall be an ex-officio member;</p> <p>(2) A member appointed under 8 (1) (a) shall have a degree from a university recognized in Kenya and experience in senior management of at least 15 years</p> <p>(3) Members of the Council listed under 8 (1) b-h shall be appointed by the Cabinet Secretary;</p> <p>(4) The persons appointed under paragraph (1) (e) shall be appointed from a list of four nominees recommended to the Cabinet Secretary and nominated after recommendation by a professional association representing the interests of veterinary surgeons countrywide. Two shall be nominated from the veterinary pharmaceutical industry and two from the training institutions.</p> <p>(5) The person appointed under paragraph (1) (f) shall be appointed from a list of two nominees recommended to the Cabinet Secretary and nominated after recommendation by a veterinary para-professional association.</p> <p>(6) The person appointed under paragraph (1) (g) shall be appointed from a list of two nominees recommended to the Cabinet Secretary and nominated by a representative farmer organization;</p> <p>(7) The nominating bodies/selection bodies envisaged under paragraphs (4) (5) and (6) shall observe Constitutional principles relating to gender, youth, persons with disability and minorities in identifying the persons.</p> <p>(8) The Cabinet Secretary shall appoint the members of the Council by notice in the Kenya Gazette.</p> <p>(9) The Council shall conduct its affairs in the manner set out in the First Schedule.</p> <p>(10) The members of the Council shall hold office for a term of three years and shall be eligible for re-appointment for one further term.</p> <p>(11) The members appointed under paragraph (1) (b), (c) and (d) may, in writing, designate representatives to attend the meetings of the Council on their behalf.</p> <p>(12) The members of the Council in paragraphs (e), (f) and (g) may—</p> <p>(a) at any time resign from office by notice in writing to the Cabinet Secretary;</p> <p>(b) be removed from office by the Cabinet Secretary, on the advice of the Council if the member –</p> <p>(i) is declared bankrupt;</p> <p>(ii) is absent from three consecutive meetings of the Council, without the permission of the Chairperson;</p>	<p>Council of the Directorate</p>

<p>(iii) is convicted of a criminal offence and, sentenced to a term of imprisonment of more than six months;</p> <p>(iv) is unable or unfit, due to physical or mental illness, to perform the functions of his office; or</p> <p>(v) has failed to comply with the provisions of Chapter Six of the Constitution</p> <p>(13) The Cabinet Secretary shall, on the recommendation of the Council, appoint a relevant person from the list of nominees to serve in the place of any member of the Council in the case of death, resignation, absence from Kenya for six consecutive months without authorization or more or removal from office under paragraph (12) (b) and the person appointed under this sub-Regulation shall serve until the end of the term of the Council.</p>	
<p>9. Pursuant to section 10 of the Act, the Council may for the effective discharge of its functions co-opt into the committees such persons with technical expertise or knowledge for the better carrying out of the functions of the Directorate.</p>	<p>Co-option of specialized persons.</p>
<p>10. The conduct and regulation of the business and affairs of the Directorate shall be as provided in the First Schedule but subject thereto, the Directorate shall regulate its own procedure.</p>	<p>Conduct of Business and Affairs of the Directorate</p>
<p>11. (1) If any person is present at a meeting of the Council or any committee at which any matter is the subject of consideration and in which matter that person or that person's spouse or relative is directly or indirectly interested in a private capacity, that person shall as soon as is practicable after the commencement of the meeting declare such interest and shall not, unless the Council or committee otherwise directs, take part in any consideration or discussion of, or vote on any question connected to such matter.</p> <p>(2) The disclosure of interest shall be recorded in the minutes of the meeting at which it is made.</p> <p>(3) A member of the Council or employee of the Directorate shall not carry out any business or trade with the Directorate.</p> <p>(4) A member of the Council or staff of the Directorate who contravenes this Regulation commits an offence and is liable, on conviction, to a fine not exceeding one hundred thousand shillings or to imprisonment for a term not exceeding twelve months or to both.</p>	<p>Conflict of Interest</p>
<p>12. (1) The Directorate shall have a common seal which shall be kept by the Chief Executive Officer.</p> <p>(2) The affixing of the seal shall be authenticated by signature of the chairperson and the Chief Executive Officer and in their absence, the signature of any other member authorized by resolution of the Council.</p>	<p>Common Seal and Logo</p>
<p>13. (1) There shall be a Chief Executive Officer who shall be competitively appointed by the Council through a competitive process and whose terms and conditions of service shall be determined by the Council in the instrument of appointment;</p> <p>(2) A person shall be qualified for appointment as a Chief Executive Officer, if that person—</p> <p>(a) is a Kenyan citizen;</p> <p>(b) holds a degree in veterinary medicine from a university recognized in Kenya;</p> <p>(c) is registered by the Kenya Veterinary Board;</p>	<p>Chief Executive Officer</p>

<p>(d) has at least ten years' professional experience in the affairs of veterinary medicines, of which at least five years are at senior management level; and</p> <p>(e) Satisfies the requirements of Chapter Six of the Constitution.</p> <p>(3) The Chief Executive Officer shall be an ex-officio member of the Council but shall have no right to vote at any meeting of the Council.</p> <p>(4) The Chief Executive Officer shall hold office for a term of three years and shall be eligible for reappointment for one further term.</p> <p>(5) The Chief Executive Officers shall, in the performance of the functions and duties of office, be responsible to the Council.</p> <p>(6) Without prejudice to the provisions of paragraph (5), the Chief Executive Officer shall—</p> <p>(a) be responsible for—</p> <p>(i) carrying into effect the decisions of the Council;</p> <p>(ii) day-to-day administration and management of the affairs of the Directorate;</p> <p>(iii) supervision of the staff of the Directorate;</p> <p>(b) be the Registrar of veterinary medicines; and</p> <p>(c) perform such other duties as may be assigned by the Council.</p>	
<p>14. (1) The Chief Executive Officer may be removed from office by the Council in accordance with the terms and conditions of service, for—</p> <p>(a) inability to perform functions of the office arising out of physical or mental infirmity;</p> <p>(b) gross misconduct or misbehavior;</p> <p>(c) incompetence or negligence of duty;</p> <p>(d) violation of the Constitution and any other written law; or</p> <p>(e) any other grounds specified in the terms and conditions of service.</p> <p>(2) Where the question of the removal of the Chief Executive Officer under paragraph (1) arises, the Council shall—</p> <p>(a) inform the Chief Executive Officer in writing of the reasons for the intended removal; and</p> <p>(b) provide the Chief Executive Officer with the opportunity to be heard in accordance with the principles of fair administrative action safeguarded under Article 47 of the Constitution.</p>	<p>Removal of the Chief Executive Officer</p>
<p>15. (1) The Directorate may employ such staff as it deems appropriate for the effective performance of its functions.</p> <p>(2) In consultation with the Salaries and Remuneration Commission, the Directorate may determine the terms and conditions of employment of the staff of the Directorate;</p>	<p>Staff of the Directorate</p>
<p>16. The members and the employees of the Directorate shall subscribe to the leadership and integrity code issued by the Directorate from time to time.</p>	<p>Code of Conduct</p>
<p>17. Nothing done by a member of the Council or an employee of the Directorate shall, if done in good faith for the purpose of executing the powers, functions or duties of the Directorate under these Regulations render such member or officer personally liable for any action, claim or demand.</p>	<p>Protection from Personal Liability</p>
<p>18. The Directorate in collaboration with a County Director may:</p> <p>(a) conduct training and create awareness on responsible use of veterinary medicines;</p> <p>(b) promote prudent use of veterinary medicines;</p>	<p>The role of County Government</p>

<p>(c) designate and establish veterinary medicine waste collection and disposal sites in consultation with the National Environmental Management Authority;</p> <p>(d) Undertake pharmacovigilance</p>	
PART III VETERINARY MEDICINES INSPECTORS	
<p>19. (1) The Directorate shall appoint duly qualified persons as veterinary medicines inspectors as it deems appropriate.</p> <p>(2) A person shall be qualified for appointment as a veterinary medicines inspector if that person —</p> <p>(a) is a veterinary surgeon or a veterinary paraprofessional; or</p> <p>(b) holds other qualification recognized by the Directorate</p>	Appointment of veterinary medicine inspectors
<p>20. (1) The Directorate shall publish in the Kenya Gazette every inspector appointed under regulation 19 and issue each inspector with an official identity card which shall have a passport size photo of the inspector, duly stamped with other necessary security features and signed by the Chief Executive Officer or his authorized agent.</p> <p>(2) Every inspector shall, in conducting inspections under these Regulations, identify himself using the identity card issued under paragraph (1).</p> <p>(3) A person who ceases to be an inspector shall surrender his identify card to the Chief Executive Officer or his authorized agent.</p>	Identification of veterinary medicines inspector
<p>21. (1) An inspector shall have the power, at all reasonable times, to—</p> <p>(a) enter upon the premises of any manufacturer, distributor or veterinary pharmacy and to inspect any books, papers, records or writings, veterinary medicines, whether patent or otherwise, for sale or used in the business; or</p> <p>(b) enter any premises in which he has reasonable cause to suspect that a breach of the law has been or is being committed, and to make such examination and inquiry and to do such other activities, including impounding and seizing suspect veterinary products, closing suspect premises and the taking of samples, as may be necessary for the purpose of ascertaining whether the provisions of these Regulations are being complied with.</p> <p>(2) An inspector shall-</p> <p>(a) for the purpose of inspecting a veterinary medicine use Form A set out in the Third Schedule; and</p> <p>(b) for any impounding of suspect veterinary medicines, use Form B set out in the Third Schedule.</p> <p>(3) An inspector shall observe confidentiality in the findings of his inspection.</p> <p>(4) An inspector shall be liable for any act of negligence he may commit in the performance of his duties.</p> <p>(5) Where an inspector has ascertained compliance of the premise, the Directorate shall issue a license as set out in Form C set out in the Third Schedule.</p>	Powers of veterinary medicines inspectors
PART IV— MANUFACTURE, IMPORTATION AND REGISTRATION OF VETERINARY MEDICINES	
<p>22. A person shall not import, manufacture, sell, transport or distribute any veterinary medicine in Kenya unless that veterinary medicine has been registered in accordance with the provisions of these Regulations.</p>	Registration of Veterinary medicines.

<p>23. A person transporting a veterinary medicine in transit shall declare the veterinary medicine at the port of entry and exit.</p>	<p>Veterinary medicines in transit</p>
<p>24. (1) A person who intends to manufacture a veterinary medicine shall make an application to the Directorate for a good manufacturing practice license and manufacturing permit.</p> <p>(2) An application for a manufacturing license under sub-regulation (1) shall be in Form D and for good manufacturing practice license in Form E as set out in the Third Schedule</p> <p>(3) An applicant under sub-regulation (1) shall, on approval of the application by the Directorate, pay the fee prescribed in the Fourth Schedule.</p> <p>(4) The Directorate, upon confirming that the applicant has satisfied the requirements for issuance of a manufacturing license, and upon payment of the fee under sub-regulation (3) issue an applicant with a manufacturing license as set out in Form F set out in the Third Schedule</p> <p>(5) The manufacturing license shall be valid for a period of one year commencing on the 1st of January and ending on the 31st of December of each year.</p>	<p>Manufacturing license.</p>
<p>25. (1) The Directorate shall, on receipt of an application made under regulation 24, before issuing a certificate of registration, cause the premises in which the manufacturing of the veterinary medicine is proposed to be conducted be inspected in order to ensure compliance to good manufacturing practices issued by the Directorate from time to time.</p> <p>(2) The inspector instructed under paragraph (1) shall submit the results of the inspection to the Directorate and the applicant in writing.</p> <p>(3) A manufacturer shall ensure that every stage in the manufacture of a veterinary medicine is carried out based on good manufacturing practices.</p> <p>(4) A manufacturer shall not manufacture a veterinary medicine unless the manufacturing plant has been inspected and licensed in accordance with these Regulation.</p> <p>(5) A person shall not use any premises, for the purposes of manufacturing, formulating, packaging, re-packaging, selling or storing veterinary medicine unless that person is in possession of a license issued under these Regulations in respect of that premises.</p> <p>(6) Where an inspector has ascertained compliance by the manufacturer, the Directorate shall issue a license as set out in Form G set out in the Third Schedule.</p> <p>(7) A person in executive authority of manufacturing company which manufactures veterinary medicines without a license commits an offence and shall be liable, on conviction, to a fine not exceeding one hundred thousand shillings or to imprisonment for a term not exceeding twelve months or to both.</p>	<p>Manufacturing of veterinary medicines.</p>
<p>26. (1) An inspector appointed under these Regulations shall have power with regard to manufacturing plants to—</p> <p>(a) enter the premises and inspect the plant and the process of manufacture intended to be employed in the manufacturing of the veterinary medicine and shall make a report to the Directorate; or</p> <p>(b) Conduct a desktop or a virtual inspection of premises provided that such inspection shall be validated at the earliest time possible;</p> <p>(c) Order the immediate closure of a manufacturing plant or the specific line whose continued operation would pose a serious threat to life and safety.</p> <p>(2) An inspector who has ordered the closure of a plant under paragraph (1)(c) shall within twenty-four hours of the closure notify the Directorate of the closure and shall provide reasons for the closure.</p> <p>(3) On receipt of the notification under paragraph (2), the Directorate shall direct the owner of the plant to take such measures as the Directorate may direct to ensure conformity with these Regulations.</p>	<p>Powers of inspectors with regard manufacturing plants.</p>

<p>(4) A manufacturer who fails to take the corrective measures outlined by the Directorate shall have the license revoked.</p> <p>(5) The Directorate shall publish in Kenya Gazette and at least one newspaper or recognized digital platform of wide national circulation the name of a manufacturing plant closed and whose license has been revoked under this Regulation and shall place a notice of the closure at the entrance of such plant.</p>	
<p>27. (1) An application for registration of a veterinary medicine shall be in accordance with Forms H1-H5 and Form I set out in the third schedule—</p> <p>(2) An applicant shall, in addition to the information required in paragraph (1), furnish such further information and material as may be required by the Directorate for the proper evaluation of the veterinary medicine in respect of which the application is made.</p> <p>(3) The Directorate shall, on approval of an application made under this Regulation register the veterinary medicine and issue a certificate in Form J1 or J2, respectively set out in the Third Schedule.</p> <p>(4) A person issued with a certificate of registration shall be deemed to have acquired market authorization for the veterinary medicine.</p> <p>(5) A certificate of registration issued under these Regulations shall, unless suspended or revoked, be in force for a period of five years.</p> <p>(6) The Directorate shall not approve an application made under paragraph (1) unless satisfied that the applicant has attained the prescribed standards and satisfied all requirements for registration.</p>	<p>Application for registration of a veterinary medicine.</p>
<p>28. (1) A person may make an application to the Directorate, for renewal of registration of a veterinary medicine in Form K1 set out in the Third Schedule.</p> <p>(2) The Directorate shall, before renewing registration under this Regulation be guided by pharmacovigilance data and information on the veterinary medicine.</p> <p>(3) An applicant shall on receipt of approval for renewal of registration from the Directorate, make payment of the fees as prescribed in the Fourth Schedule.</p> <p>29. (1) A person may make an application by 31st of December of every year to the Directorate, for retention of a veterinary medicine in Form K2 set out in the Third Schedule.</p> <p>(a) The retention register shall be published by 31st of March every year.</p> <p>(b) the Council shall consider late applications for retention upon payment of a fee as set out in the Fourth Schedule</p> <p>(2) The Council shall, before retaining a veterinary medicine under this Regulation review reports from post market surveillance of the veterinary medicine</p> <p>(3) An applicant shall on receipt of approval for retention from the Directorate, make payment of the fees as prescribed in the Fourth Schedule.</p>	<p>Renewal and Retention of Veterinary Medicine</p>
<p>30. (1) The Directorate shall designate laboratories for purposes of the required tests under these regulations.</p> <p>2) The Directorate shall publish on their website the list of designated laboratories from time to time.</p>	<p>Designated laboratory</p>
<p>31. (1) The Directorate may require that a clinical and non-clinical trial and toxicity testing be done before the registration of a veterinary medicine in Kenya whose active ingredient has not been previously registered in Kenya, and for which there are no existing mutual recognition agreements with recognized veterinary medicine regulatory authorities in other countries.</p> <p>(2) Despite paragraph (1) a veterinary pesticide shall not be registered unless an efficacy and an acute toxicological study is carried out by a designated laboratory.</p>	<p>Clinical and nonclinical trials and toxicity testing</p>

<p>(3) A person who desires to conduct a clinical and non-clinical trial and toxicity testing shall apply to the Directorate for designation of the laboratory where the trial will be conducted in Form L set out in Third schedule.</p> <p>(4) The cost of any clinical trial or toxicity testing shall be borne by the applicant.</p>	
<p>32. (1) A veterinary medicine shall not be registered unless a laboratory analysis has been carried out by a designated laboratory.</p> <p>(2) A person who intends to register a veterinary medicine shall submit to the Directorate a certificate of analysis from a designated laboratory together with the application for registration of the veterinary medicine.</p>	<p>Conditions for registration of veterinary medicines</p>
<p>33. (1) There is hereby established a standing committee of the Council to be known as the Veterinary Medicines Registration Committee.</p> <p>(2) The Registration Committee shall be responsible for matters relating to registration of veterinary medicines under these Regulations and in particular shall be responsible for—</p> <p>(a) recommending veterinary medicines for registration to the Council; and</p> <p>(b) issuing provisional approval pending the issuance of the veterinary medicines registration certificate by the Directorate.</p> <p>(3) A provisional certificate issued under paragraph (2)(b), and using Form H1 in the Third Schedule, shall be valid for a period of not more than three months until the certificate is issued whichever comes earlier.</p> <p>(4) The Directorate shall consider an application made under this Regulation, and if satisfied that the applicant has fulfilled all the requirements, shall register the veterinary medicine in accordance with Form M set out in the Third Schedule.</p> <p>(5) Upon registration of a veterinary medicine under paragraph (4), the applicant shall be issued with a certificate of registration in Form J1 or J2 set out in the Third Schedule.</p> <p>(6) The Directorate may, while considering a veterinary medicine for registration under paragraph (4), approve the details as supplied by the applicant or approve it with such modifications as it may consider appropriate in respect of the following particulars—</p> <p>(a) the trade name under which the veterinary medicine may be sold;</p> <p>(b) the labeling;</p> <p>(c) the statement of the representations to be made for the promotion of the veterinary medicine in respect of the-</p> <p>(i) claim to be made for the veterinary medicine;</p> <p>(ii) route of administration;</p> <p>(iii) dosage;</p> <p>(iv) contra-indications, side effects and precautions, if any;</p> <p>(v) package size;</p> <p>(vi) withdrawal period for food animals;</p> <p>(vii) proposed category; and</p> <p>(viii) shelf life.</p> <p>(ix) storage requirements</p>	<p>Veterinary Medicines Registration Committee</p>
<p>34. (1) The Directorate shall, if not satisfied that the applicant has fulfilled all the requirements for registration, reject the application for the registration of the veterinary medicine and inform the applicant, in writing, the reasons for rejection.</p> <p>(2) The applicant if not satisfied with the decision of the Directorate on the outcome of registration of their Veterinary medicine may appeal in writing within 14 days and on payment of the fees stipulated in the Fourth Schedule.</p> <p>(3) The Directorate shall communicate the outcome of the appeal to the applicant within 90 days from the date of appeal.</p>	<p>Rejection of application for registration of a veterinary medicine.</p>

<p>35. (1) The Directorate may, before registering a new veterinary medicine for which research has been conducted in another country and its efficacy, safety, and quality established in that country, require an investigation on the pharmacological and other aspects of the veterinary medicine to be conducted and clinical trials to be carried out as necessary to establish its safety, efficacy, quality and where applicable the biological availability to be established under local conditions.</p> <p>Provided that where the Directorate after investigation and inquiry with the competent authority of the source country determines that the authorization of the veterinary medicine in that country meets the same objectives on efficacy, safety and quality as these regulations, it shall register the veterinary medicine without repeating the pharmacological assessment and clinical trials in Kenya.</p> <p>(2) Despite paragraph (1), the Directorate may register a new veterinary medicine and require the investigations and clinical trials specified therein to be conducted after its registration.</p>	<p>Registration of veterinary medicine researched outside Kenya.</p>
<p>36. (1) The Directorate may suspend or revoke a certificate of registration issued under these Regulations for such period as the Directorate may determine.</p> <p>(2) The Directorate shall not revoke or cancel the certificate of registration unless—</p> <p>(a) where matters stated in the application on which the certificate of registration was granted were false or incomplete in any particular material;</p> <p>(b) where provision of the certificate of registration has to a material extent been contravened by the holder of the certificate;</p> <p>(c) where the premises on which, or on part of which, a veterinary medicine is manufactured, assembled or stored by or on behalf of the holder of the certificate of registration are unsuitable for the manufacturing, assembling or storage of veterinary medicines; or</p> <p>(d) where new information has been discovered by the Directorate which renders the veterinary medicines unsafe or dangerous. Provided that any finding that a registered veterinary medicine has shown adverse effects during manufacture, distribution or use in animals shall be reported by the Directorate to the Director without delay.</p> <p>(3) Before the Directorate revokes the license, a notice of 14 days shall be given in writing to the holder of market authorization.</p> <p>(4) The notice in paragraph (3) shall contain the reasons for the intended revocation and where necessary require the holder to address the issues of concern within 30 days.</p> <p>(5) Where the holder has not addressed the issues in paragraph (4) the Directorate shall revoke the market authorization.</p> <p>(6) Where a certificate has been revoked under paragraph (1), the Directorate shall on delivery of the information to the manufacturer-</p> <p>(a) inspect the manufacturing plant to ensure all the medicine or the relevant batch has been destroyed;</p> <p>(b) disseminate the information to the public through a newspaper advertisement in at least two daily newspapers of nationwide circulation or a recognized digital platform; and</p> <p>(c) shall direct the applicant to recall any medicine which has been distributed.</p> <p>(7) an applicant who fails to comply with sub-regulation (6) (c) commits an offence and shall upon conviction be liable to a fine not exceeding Ksh one hundred thousand or imprisonment for a period not exceeding twelve months or both.</p>	<p>Suspension and revocation of certificate of registration.</p>
<p>37.</p> <p>(1) The Directorate shall carry out pharmacovigilance through receiving reports from manufacturers, wholesalers, retailers, users and animal owners on veterinary medicines as well as through regular surveys or on the advice of the Director</p>	<p>Pharmacovigilance</p>

<p>(2) In carrying out pharmacovigilance under paragraph (1), the Directorate shall take requisite measures including-</p> <ul style="list-style-type: none"> (a) Taking samples of veterinary medicines; (b) Having the samples tested in a designated laboratory to ascertain the concentration of the active ingredient and other pharmacological attributes; (c) Taking samples of various animal products and by-products and testing them for level of concentration of veterinary medicines if any; (d) Carrying out discussions, interviews with animal owners and users of veterinary medicines to find out their views on regulation of veterinary medicines; (e) Assessing product information in the leaflets of veterinary medicines in the market <p>(3) The Directorate shall publish a summary of the findings of pharmacovigilance in its website while taking measures to ensure corrective actions as necessary.</p> <p>(4) The manufacturer shall carry out pharmacovigilance on their products and report to the Directorate using Form N in the third schedule.</p>	
<p>38. (1) The Directorate may grant the renewal of registration as provided under regulation 28 for a period not exceeding five years.</p> <p>(2) On the expiry of five years a veterinary medicine may be retained in the register upon an application Form K1 in the third schedule made by the certificate holder which shall—</p> <ul style="list-style-type: none"> (a) include a declaration that the requirements met by the veterinary medicine during registration has not changed; and (b) an application for renewal of registration shall be accompanied by pharmacovigilance data. 	<p>Period for renewal of registration and retention of veterinary medicine.</p>
<p>39. Where information submitted by a market authorization holder in support of an application for registration of a veterinary medicine has changed or is proposed to change either in part or in full, the applicant shall submit such changes for consideration by the Directorate by filling Form O in the Forth Schedule.</p>	<p>Variation</p>
<p>PART V – CLASSIFICATION AND CATEGORIZATION OF VETERINARY MEDICINES</p>	
<p>40. (1) The classification of the veterinary medicines is as set out in Part I of the Second Schedule.</p> <p>(2) The Cabinet Secretary may, on the advice of the Council, vary the classification of the various veterinary medicines depending on the therapeutic use and current information for the medicine.</p>	<p>Classification of Veterinary Medicines.</p>
<p>41. (1) The categorization of veterinary medicines is as set out in Part II of the Second Schedule.</p> <p>(2) The categories of veterinary medicines are as follows; —</p> <ul style="list-style-type: none"> (a) Category I relating to prescription only medicine. This shall comprise of two sub-categories as follows— <ul style="list-style-type: none"> i) Sub-category IA- relating to Controlled Veterinary Medicines. These are products which contain narcotic or psychotropic substances or other substances that are harmful to health in small quantities; ii) Sub-category IB -relating to other prescription only medicines. These are products intended for administration following a diagnosis or clinical assessment by a veterinary surgeon or dispensed by a veterinary surgeon or a person with equivalent qualifications 	<p>Categorization of Veterinary Medicines. Category I</p>

<p>(b) Category II veterinary medicines in respect of which special precautions shall be taken in order to avoid any unnecessary risk to the target species, the person administering the products to the animal and the environment; Provided that the requirement in this paragraph shall not apply if all the following criteria are met—</p> <ul style="list-style-type: none"> (i) the administration of the veterinary medicine is restricted to formulations requiring no particular knowledge or skill in using the product; (ii) the veterinary medicine does not present a direct or indirect risk, even if administered incorrectly, to the animal or animals treated, to the person administering the product or to the environment; (iii) the summary of product characteristics of the veterinary medicine does not contain any warnings of potential serious side effects deriving from its correct use; (iv) the veterinary medicine or any other product containing the same active substance has not previously been the subject of frequent serious adverse reaction; (v) the summary of product characteristics does not refer to contra-indications related to other veterinary medicine commonly used without prescription; (vi) the veterinary medicine is not subject to special storage conditions; (vii) there is no risk for consumer safety as regards residues in food obtained from treated animals even where the veterinary medicines have been used incorrectly; and (viii) there is no risk to human or animal health as regards the development of resistance to antimicrobials or anti-helminthic substances even where the veterinary medicine containing those substances is used incorrectly; and (ix) veterinary medicines that may cause effects that impede or interfere with subsequent diagnostic or therapeutic measures. <p>(d) Category III relating to authorized veterinary medicine general sales list provided for in the second schedule and includes:</p> <ul style="list-style-type: none"> (i) pest control veterinary medicines provided that the medicine is sold in the original package without re-packaging and with an intact label. (ii) endoparasiticide veterinary medicines considered safe for use in food animals; (iii) endoparasiticide veterinary medicines for use in non-food animals; or (iv) any other product the Directorate may prescribe. <p>(e) Category IV which includes alternative veterinary medicine general sales list provided for in the second schedule.</p>	<p>Category II</p>
<p>42. (1) A veterinary pesticide shall be—</p> <ul style="list-style-type: none"> (a) sold only in the original sealed and labeled package as registered by the Directorate; (b) stored in accordance with the instructions on the label on the original container; and (c) used according to the instructions on the label. <p>(2) The empty container of a veterinary pesticide shall be disposed in accordance with the instructions given on the label.</p> <p>(3) A person who removes or defaces a label on a veterinary pesticide or package commits an offence.</p> <p>(4) A person who sells, dispenses or otherwise gives out a veterinary pesticide in contravention of this Regulation commits an offence and shall be liable, on conviction, to a fine not exceeding one hundred thousand shillings or to imprisonment for a term not exceeding twelve months or to both.</p>	<p>Use of veterinary pesticides.</p>
<p>43. (1) (1) A veterinary pharmaceutical shall be—</p> <ul style="list-style-type: none"> (a) sold only in the original sealed and labeled package as registered by the Directorate; (b) stored in accordance with the instructions on the label on the original container; and (c) used according to the instructions on the label. 	<p>Use of veterinary pharmaceuticals</p>

<p>(2) The empty containers and packaging materials of veterinary pharmaceutical shall be disposed in accordance with the Waste Management Act.</p> <p>(3) A person who removes or defaces a label on a veterinary pharmaceutical or package commits an offence.</p> <p>(4) A person who sells, dispenses or otherwise gives out a veterinary pharmaceutical in contravention of this Regulation commits an offence and shall be liable, on conviction, to a fine not exceeding one hundred thousand shillings or to imprisonment for a term not exceeding twelve months or to both.</p>	
PART VI— VETERINARY PHARMACY	
<p>44. (1) A veterinary pharmacy shall satisfy the following minimum standards—</p> <ul style="list-style-type: none"> (a) be located away from known fire hazards; (b) be a separate entity from other veterinary operations such as veterinary clinic, ambulatory and laboratory services; (c) be separated from non-complimentary businesses within the same business; (d) have restricted access by personnel to Category I and II veterinary medicine; and (e) be vermin-proofed, including protection against insects and rodents; <p>(2) A veterinary pharmacy shall—</p> <ul style="list-style-type: none"> (a) demonstrate adequate security for the safety of veterinary medicine; (b) demonstrate appropriate storage conditions that shall maintain the temperature, lighting and humidity requirements as prescribed in the manufacturers’ specifications of veterinary medicines; (c) have the floor and the wall of the building constructed from materials that are easy to clean, impervious and resistant to corrosion by chemicals; (d) have lockable safety cabinets to protect the controlled veterinary medicines; (e) provide the personnel with protective clothing for use only within the premises; (f) be of appropriate size and have sufficient space for carrying out of all necessary operations provided for the orderly receipt, warehousing and dispatch of the various classes of veterinary medicines and, in particular, a quarantine area for isolation when necessary, including isolation of faulty packs and recalled or expired veterinary products; (g) provide a disposal system, acceptable to the Directorate, for safe disposal of expired veterinary medicines; (h) be operated by competent staff as provided for in the license; (i) display warning notices indicating hazardous areas; (j) label the various sections in the business; (k) store veterinary medicines only in the designated areas, which shall be labeled; (l) have emergency lighting, firefighting equipment and fully equipped first aid kit; (m) display emergency protocols within the veterinary pharmacy advising personnel on procedures to follow in case of emergencies; (n) display standard operating procedures; (o) retain records of the movement of all veterinary medicines for at least ten years. Such records shall include the identity of the immediate supplier of the veterinary medicine to the veterinary pharmacy and the immediate purchase of the veterinary medicine from the veterinary pharmacy; and (p) provide separate sanitary facilities for each gender. 	<p>Standards of Veterinary Pharmacy</p>
<p>45. A person who is a veterinary surgeon and veterinary paraprofessional or holds an equivalent qualification in matters pertaining to veterinary medicines as determined by the Directorate, may apply to the Directorate for a permit to undertake a veterinary pharmacy business for the category of veterinary medicine approved for that qualification.</p>	<p>Qualifications to operate a veterinary pharmacy.</p>

<p>46. (1) The Directorate shall have power to approve any of the following types of veterinary pharmacy businesses—</p> <p>(a) wholesaling of veterinary medicines; and</p> <p>(b) retailing of veterinary medicines.</p> <p>(2) Upon approval of the veterinary pharmacy business specified under paragraph (1), the Directorate shall register the veterinary pharmacy in Form P set out in the Third Schedule.</p>	<p>Directorate to approve veterinary pharmacy businesses.</p>
<p>47. (1) A person shall not carry out the business of veterinary pharmacy unless he holds a valid veterinary pharmacy license issued by the Directorate.</p> <p>(2) A person who intends to carry out the business of veterinary pharmacy shall make an application in Forms Q1 and Q2 respectively of the Third Schedule.</p> <p>(3) The Directorate shall issue a veterinary pharmacy license if the premises in which the applicant intends to operate has been approved in accordance with these Regulations.</p> <p>(4) An applicant under paragraph (2) shall, on approval of the application, by the Directorate, pay the fee prescribed in the Fourth Schedule.</p> <p>(5) The Directorate, upon confirming that the applicant has satisfied the conditions of a license issue an applicant with a veterinary pharmacy license as set out in Form R1 set out in the Third Schedule for retail pharmacy and Form R2 for wholesale pharmacy</p> <p>(6) The veterinary pharmacy license shall be valid for a period of one year commencing on the 1st of January and ending on the 31st of December of each year.</p> <p>(7) The Directorate shall publish on a quarterly basis in its website, the list of licensed veterinary pharmacy businesses.</p> <p>(8) A person who conducts the business of veterinary pharmacy in premises not registered by the Directorate under these Regulations commits an offence, and shall be liable, on conviction, to a fine not exceeding one hundred thousand shillings or to imprisonment for a term not exceeding twelve months or to both.</p>	<p>Veterinary pharmacy license</p>
<p>48. (1) A person who carries on the business of a veterinary pharmacy shall display the veterinary pharmacy license on a conspicuous place within the premises in which the business is being carried out.</p> <p>(2) A person who contravenes the provisions of this Regulation commits an offence and shall be liable, on conviction, to a fine not exceeding five thousand shillings or to imprisonment for a term not exceeding one month or to both.</p>	<p>Veterinary pharmacy license to be displayed</p>
<p>49. A person who intends to trade in veterinary medicines, in bulk, shall make an application to the Directorate for a wholesale dealers license and support the application with the following—</p> <p>(a) a certified copy of the certificate of registration or incorporation in accordance with the laws of Kenya;</p> <p>(b) provide evidence that the business is under the management of a supervisor who—</p> <p>(i) is a registered veterinary surgeon permitted to carry out the business of veterinary pharmacy; and</p> <p>(ii) is a member of the Board of directors of the body corporate.</p>	<p>Wholesale dealers license</p>
<p>50. A manufacturer or a wholesaler may apply to the Directorate for a license to carry out retail veterinary pharmacy business.</p>	<p>Retail pharmacy license</p>
<p>51. (1) A veterinary pharmacy may be conducted alongside complimentary businesses including the sale of human medicines, horticultural chemicals, agro-forestry chemicals and fertilizer, animal foodstuffs, seeds and agricultural equipment.</p>	<p>Complementary businesses</p>

<p>(2) The building or premises of a veterinary pharmacy stocking or trading in complimentary businesses referred to in paragraph (1), shall be built or adapted in such manner as to provide a separate and distinct partition for the veterinary medicines from any other products.</p> <p>(3) In addition to the provisions of paragraph (2), the premises shall be built or adapted in such manner as to provide separate and distinct partitions for veterinary pesticides such that no mixing of the veterinary pesticides with other veterinary medicines may occur.</p>	
<p>52. (1) A veterinary medicine shall be supplied or distributed only through a business registered as a veterinary pharmacy business</p> <p>(2) A veterinary pharmacist who dispenses a veterinary medicine belonging to Category I or II to any member of the public without a prescription, commits an offence and shall be liable, on conviction, to a fine not exceeding one hundred thousand shillings or to imprisonment for a term not exceeding twelve months or to both.</p>	<p>Stock, supply and distribution of veterinary medicine</p>
<p>53. (1) A holder of a market authorization may apply to the Directorate for a wholesale dealers license to authorize him to import or export the veterinary medicine specified in the authorization.</p> <p>(2) A person who intends to import or export a veterinary medicine shall apply to the Directorate for a permit in Form S set out in the Third Schedule.</p> <p>(3) The Directorate shall in determining the application under paragraph (2) consider whether the applicant has met the conditions for importation and exportation in these Regulations, and if so, shall on payment of the prescribed fee, issue the applicant with an import or export permit in Form T set out in the Third Schedule.</p> <p>(4) An authorized wholesale dealer may import a veterinary medicine if—</p> <p>(a) the authorization covers the veterinary product; and</p> <p>(b) the wholesale dealer has acquired the written consent of the holder of the market authorization in writing before importation.</p> <p>(5) A veterinary surgeon may, with approval of the Directorate, import an orphan veterinary medicine.</p>	<p>Authorization to import or export veterinary medicine</p>
<p>PART VII: FINANCIAL PROVISIONS</p>	
<p>54. (1) The funds of the Directorate shall comprise of –</p> <p>(a) such monies as may be appropriated by Parliament for the purposes of the Directorate;</p> <p>(b) such monies as may accrue to or vest in the Directorate in the course of the exercise of its functions under these Regulations; and</p> <p>(c) monies from any other source provided for, donated or lent to the Directorate.</p>	<p>Funds of the Directorate</p>
<p>55. The financial year of the Directorate shall be the period of twelve months from first July to thirtieth of June.</p>	<p>Financial year</p>
<p>56. (1) Three months before the commencement of each financial year, the Directorate shall cause to be prepared estimates of revenue and expenditure of the Directorate for that year.</p> <p>(2) The annual estimates shall make provision for all the estimated expenditure of the Directorate for the financial year concerned, and in particular shall provide for—</p> <p>(a) the payment of salaries, allowances and other charges in respect of the staff of the Directorate;</p> <p>(b) the payment of pensions, gratuities and other charges in respect of retirement benefits which are payable out of the funds of the Directorate;</p> <p>(c) the proper maintenance of buildings and grounds of the Directorate;</p>	<p>Annual estimates</p>

<p>(d) the acquisition, maintenance, repair and replacement of the equipment and other movable property of the Directorate; and</p> <p>(e) the creation of such reserve funds to meet future or contingent liabilities in respect of retirement benefits, insurance or replacement of buildings or equipment or in respect of such other matter as the Directorate may find appropriate.</p> <p>(3) The annual estimates shall be approved by the Council before the commencement of the financial year to which they relate and shall be submitted to the Cabinet Secretary for approval.</p> <p>(4) The Directorate shall not increase any sum provided in the estimates without the consent of the Cabinet Secretary.</p>	
<p>57. The Directorate may invest any of the funds of the Directorate in a manner approved by the National Treasury for the investment of trust funds.</p>	<p>Investment of funds</p>
<p>58. (1) The Directorate shall cause to be kept all proper books and records of accounts of the income, expenditure, assets and liabilities of the Directorate.</p> <p>(2) The accounts of the Directorate shall be audited in accordance with the Public Finance Management Act, 2012 (No. 18 of 2012).</p>	<p>Accounts and Audit</p>
<p>PART VIII: OFFENCES</p>	
<p>59. A person commits an offence if that person—</p> <p>(a) imports, exports, manufactures, stores, distributes, sells or otherwise handles a veterinary medicine that has not been registered or issued with a provisional registration certificate under these Regulations;</p> <p>(b) imports a veterinary medicine without a permit issued under these Regulations;</p> <p>(c) manufactures, stores, distributes or sells a veterinary medicine in premises which have not been registered under these Regulations;</p> <p>(d) presents for sale or distribution, expired, adulterated, falsified, Counterfeit or unlabeled veterinary medicines;</p> <p>(e) sells or handles a veterinary medicine in any form other than the original sealed and labeled package, as registered with the Directorate;</p> <p>(f) sells or distributes a veterinary medicine in any other area other than a registered premise;</p> <p>(g) supplies human medicinal product for administration to an animal in contravention of these Regulations;</p> <p>(h) is in possession of a Category I or Category II veterinary medicine other than in accordance with these Regulations;</p> <p>(i) advertises a veterinary medicine in contravention of these Regulations;</p> <p>(j) buys a veterinary medicine for resale in bulk while not being in possession of a wholesale dealer permit issued under these Regulations;</p> <p>(k) sells a veterinary medicine to the public while not being in possession of a retail dealer’s permit issued in accordance with these Regulations;</p> <p>(l) obstructs or fails to provide any information to the Council or veterinary medicine inspector in the performance of their lawful duties under these Regulations;</p> <p>(m) provides the Council or inspector with false or misleading information;</p> <p>(n) operates a veterinary pharmacy after it has been closed by an inspector; or</p> <p>(o) contravenes any provision of these Regulations.</p>	<p>Offences</p>

<p>60. If an institution commits an offence under these Regulations, any officer, director or agent of the corporation who directed, authorized, assented to, acquiesced in, or participated in the commission of the offence shall be a party to and shall be considered to have committed the offence and shall be liable on conviction to the punishment provided for the offence, whether or not the corporation has been prosecuted or convicted.</p>	<p>Officers of corporations</p>
<p>61. A member of the Council or staff of the Directorate, who— (a) being in possession of confidential information, however obtained without authorization of the Directorate— (i) divulges it; or (ii) attempts, offers or threatens to divulge it; or (b) willfully obtains or seeks to obtain confidential information to which he is not entitled other than in accordance with these Regulations or other written law, commits an offence.</p>	<p>Passing confidential information without authorization</p>
<p>62. A person who contravenes these Regulations where no penalty has been prescribed, shall on conviction be liable to a fine not exceeding one hundred thousand shillings or to imprisonment for a term not exceeding twelve months, or to both.</p>	<p>Penalties</p>
<p>PART IX— GENERAL PROVISIONS</p>	
<p>63. (1) A person who intends to advertise a veterinary medicine, shall make an application to the Directorate using Form U in the third schedule for authority to advertise. (2) The Directorate may, on payment of the requisite fee and subject to such conditions as the Directorate or these Regulations may impose, grant the authorization applied for under paragraph (1) in Form V in the third schedule. (3) An advertisement for a veterinary medicine shall not be misleading or contain any medicinal claim that is not in the summary of the product characteristics registered with the Directorate. (4) A veterinary medicine listed under Category I and II shall not be advertised except to an individual veterinary surgeon or a gathering of veterinary surgeons. (5) A veterinary medicine listed in Category III and IV may be advertised to general members of the public.</p>	<p>Advertising standards for veterinary medicines.</p>
<p>64. (1) These Regulations do not apply to— (a) an inactivated autogenous vaccine that is manufactured, on the instructions of a veterinary surgeon, from pathogens or antigens obtained from an animal and used for the treatment of that animal or— (i) other animals on the same site; (ii) animals intended to be sent to those premises; or (iii) animals on a site that receives animals from those premises; or (b) animal foodstuff with no therapeutic claim.</p>	<p>Exemptions to Regulations</p>
<p>65. The Directorate shall have the discretion to— (a) approve the importation and use of any veterinary medicine for handling emergency situations; (b) restrict the use of any specified veterinary medicine.</p>	<p>Discretion of the Directorate</p>

<p>66. (1) A person who has been issued with a certificate of authorization under these Regulations may, if the certificate of authorization is defaced, damaged or lost, on application to The Directorate and on payment of the prescribed fee, be issued with a copy of the certificate.</p> <p>(2) The copy of a certificate of authorization issued under paragraph (1) shall-</p> <p>(i) be issued only where the document is in force at the time the application is made;</p> <p>(ii) be valid for the same period as the original document; and</p> <p>(iii) bear the words “DUPLICATE COPY”.</p> <p>(3) Any licenses, certificates and permits issued under these regulations shall not be transferrable without the approval of the Directorate.</p>	<p>Copy of certificate or authorization</p>
<p>67. (1) The Directorate shall make reports under these regulations to the Cabinet Secretary at least once a year.</p> <p>(2) The Directorate shall prepare periodic reports and publish in their website for public information.</p>	<p>Reports</p>
<p>68. Any fees payable under these Regulations is as set out in the Fourth Schedule.</p>	<p>Fees</p>
<p>69. These Regulations shall supersede any other Regulations on matters concerning veterinary medicines.</p>	<p>Supersession</p>
<p>70. Upon the commencement of these Regulations any certificate, license or permit in force shall be deemed to have been issued under these Regulations and shall remain in force until its expiry.</p>	<p>Transition and validity of certificates, licenses and permits</p>

**FIRST SCHEDULE
CONDUCT OF THE AFFAIRS OF THE COUNCIL**

(r.8 (9))

1. The Council shall meet at least four times in a year and not more than eight times a year, except in case of an emergency, for the transaction of its business, and such meetings shall be held at such places and times and on such days as the Council may determine.

Meetings of the Council

2. (1) Notice and agenda of Council and committee meetings will issue from Chief Executive Officer as directed by the chairperson of the Council

Notice and Agenda of meetings

(2) The Council shall at its first meeting elect its vice chairperson from among members.

(3) The Chairperson shall preside at all meetings of the Council at which he is present, and in case of his absence the vice chairperson shall preside, but in the absence of both the chairperson and vice- chairperson, members present and constituting a quorum shall elect one among their number to be the chairperson for purposes of the meeting.

3. The quorum of a meeting of the Council shall be five, at least three of whom shall be veterinary surgeons.

Quorum

4. The decisions of the Council shall be by a simple majority of the votes of the members present, but in the case of an equality of votes, the Chairperson or person presiding shall have a casting vote.

Decisions of Council

5. (1) The Minutes of each meeting shall be kept in the minute book, after they have been confirmed by the Council and signed by the Chairperson at a subsequent meeting of the Council. **Minutes**
(2) The deliberations and minutes of meetings of the Council shall be confidential.
6. No proceedings of the Council shall be invalid by reason only of a vacancy among the members thereof. **Vacancy not to invalidate proceedings**
7. Subject to this Schedule, the Council may determine its own procedure. **Council to determine own procedure**
8. The Council may invite any person to participate in its deliberations but a person who has been invited shall have no right to vote. **Invitation of other persons**

SECOND SCHEDULE (r.40(1) & r.41(1))

PART I-CLASSES OF VETERINARY MEDICINES

1. List of veterinary pharmaceuticals.
 - (i) Antimicrobials
 - (ii) Antiparasitic
 - (iii) Analgesics and anti-inflammatories
 - (iv) Drugs acting on the nervous system
 - (v) Cytotoxic agents
 - (vi) Other systemic therapeutic agents
 - (vii) Local therapeutic agents

2. List of biologicals
 - (i) Vaccines.
 - (ii) Toxoids.
 - (iii) Antisera.
 - (iv) Antigens.
 - (v) Probiotics and enzymes.

(vi) Hormones.

3. List of feed additives

(i) Vitamins.

(ii) Minerals.

(iii) Amino acids.

(iv) Oils.

(v) Sugars.

4. Equipment and Devices.

(i) Surgicals equipment.

(ii) Veterinary medicine administration devices.

(iii) Any other equipment and device of veterinary relevance

5. Biocidals

(i) Disinfectants

(ii) Antiseptics

6. List of alternative and other non-conventional medicines.

(i) Preventive

(ii) Curative

(iii) Performance enhancers

(iv) Alternative medicines from plants or animals or environment origin

7. List of poisons.

(i) Acaricides

(ii) Molluscicides

(iii) Insecticides

(iv) Rodenticides

(v) Avicides

(vi) Any other veterinary pesticides

(vii) Any other ecto-and endo-parasiticides

(viii) substances used for euthanasia

PART II-CATEGORIES OF VETERINARY MEDICINES

CATEGORY I

(a) Prescription Only Medicine–Veterinary surgeon (abbreviated to POM-V);

Category I A POM-V Controlled Veterinary Medicine

1. Amphetamine
2. Apomorphine; its salts
3. Butorphanol
4. Carfentanil
5. Coca, alkaloids of.
6. Cocaine.
7. Thiofentanil
8. Etorphine
9. Fentanyl; its salts
10. Etoxidine;
11. Morphine and its derivatives.
12. Alfentanil
13. Methadone (amidone); its salts
14. Pethidine
15. Phenomorphan; its salts.
16. Phenoperidine; its salts.
17. Strychnine.
18. Sufentanil
19. Any other veterinary medicine relevant in the category

Category IB – Other POM - V

- (1) Alkali fluorides, other than those specified in Part II of this List.
- (2) Chlorpropamide; its salts.
- (3) Acetaminophen
- (4) Acetohexamide.
- (5) Adrenal hormones
- (6) Adrenaline
- (7) Alkaloids, the following; their salts, simple or complex.
- (8) Amidopyrine; its salts; amidopyrine sulphonates; their salts.

- (9) Amino-alcohols esterified with benzoic acid, phenylacetic acid, phenylpropionic acid, cinnamic acid or the derivatives of these acids, their salts.
- (10) Amitriptyline; its salts.
- (11) Atipemazole
- (12) Atropine.
- (13) Azaperone
- (14) B-Aminopropylbenzene and B-aminoisopropylbenzene and any compound structurally derived from either of those substances by substitution in the chain or by ring closure therein (or by both such substitution and such closure), except ephedrine, N-methylephedrine, N-diethylaminoethylephedrine, phenylpropanolamine, and prenylamine; any substance falling within this item.
- (15) Barbituric acid; its salts; derivatives of barbituric acid; their salts; compounds of barbituric acid, their salts, their derivatives, their salts, with any other substances.
- (16) Belladonna, alkaloids of.
- (17) Benzoestrol.
- (18) Busulphan; its salts.
- (19) Carbachol.
- (20) Carbinoxamine.
- (21) Chlorcyclizine.
- (22) Chlordiazepoxide; its salts.
- (23) Chlormethiazole; its salts.
- (24) Chloroform.
- (25) Chlorothiazide.
- (26) Chlorpheniramine.
- (27) Codeine.
- (28) Curare, alkaloids of; curare bases.
- (29) Cyclizine.
- (30) Diclofenac
- (31) Dehydroemetine; its salts.
- (32) Derivatives of stilbene, dibenzyl or naphthalene with oestrogenic activity; their

esters.

- (33) Detomidine
- (34) Dextromethorphan; its salts.
- (35) Diazepam.
- (36) Diethylcarbamazine.
- (37) Digitalis, glycosides of; other active principles of digitalis.
- (38) Diphenhydramine.
- (39) Disulfiram.
- (40) Doxapram
- (41) Doxylamine.
- (42) Ecothiopate iodide.
- (43) Ergonine; its esters.
- (44) Ergot, alkaloids of, homologues and hydrogenated.
- (45) Ethionamide.
- (46) Fluoroacetamide.
- (47) Fluoroacetanilide.
- (48) Furethidine; its salts.
- (49) Gallamine; its salts.
- (50) Glutethimide; its salts.
- (51) Haloperidol.
- (52) Homatropine.
- (53) Hyaluronidase
- (54) Hydroxypethidine; its salts.
- (55) Hyoscine.
- (56) Hyoscyamine.
- (57) Imipramine; its salts.
- (58) Indomethacin; its salts.
- (59) Insulin.
- (60) Isoniazid.
- (61) Ketamine

- (62) Medetomidine
- (63) Mephenesin; its esters.
- (64) Meprobamate.
- (65) Mercaptopurine; its salts; derivatives of mercaptopurine; their salts.
- (66) Metformin; its salts.
- (67) Methocarbamol.
- (68) Midazolam
- (69) Monofluoroacetic acid; its salts.
- (70) Nalorphine; its salts
- (71) Diprenorphin
- (72) Naloxone
- (73) Naltrexone
- (74) Ouabin.
- (75) Oxyphenbutazone.
- (76) p-Aminobenzenesulphonamide; its salts, derivatives of p-aminobenzenesulphonamide having any of the hydrogen atoms of the p-amino group or of the sulphonamide group substituted by another radical; their salts.
- (77) p-Aminobenzoic acid, esters of; their salts.
- (78) p-Amino-salicylic acid; its salts; any preparation of p-Amino salicylic acid; its salts.
- (79) Parenteral Antibiotics.
- (80) Parenteral Anti-histamine substances, the following; their salts; their molecular compounds—
- (81) Parenteral Arsenical substances
- (82) Pephazine
- (83) Phenamidine; its salts.
- (84) Phenazocine; its salts.
- (85) Phencyclidine; its salts.
- (86) Phenformin; its salts.
- (87) Phenindamine.

- (88) Pheniramine.
- (89) Phenothiazine, derivatives of
- (90) Phenylbutazone.
- (91) Phenyltoloxamine.
- (92) Pholcodine; its salts.
- (93) Phosphorus injectable
- (94) Picrotoxin.
- (95) Pituitary hormones.
- (96) Promethazine.
- (97) Quinapyramine and analogous substances; their salts.
- (98) Quinuronium; its salts.
- (99) Rauwolfia, alkaloids of; their derivatives.
- (100) Steroid compounds with androgenic or oestrogenic or progestational activity; their esters.
- (101) Suxamethonium
- (102) Thallium, salts of.
- (103) Thyroid hormones.
- (104) Tolbutamide.
- (105) Tiletamine; its salts.
- (106) Tripeleennamine
- (107) Vaccines,
- (108) Xylazine
- (109) Yohimbine.
- (110) Zoletil
- (111) Zuclopenthixol
- (112) Any other veterinary medicine relevant in the category

CATEGORY II –PRESCRIPTION ONLY MEDICINE (POM-VT)

Prescription Only Medicine–Veterinary surgeon

- (1) Aconite.
- (2) Androgenic, oestrogenic and progestational substances,

- (3) Antibiotics
- (4) Anti-histamine substances, the following; their salts; their molecular compounds
- (5) Arsenic.
- (6) Atropine.
- (7) Barbiturates.
- (8) Belladonna, alkaloids.
- (9) Benzene derivatives.
- (10) Benzimidazoles
- (11) Busulphan; its salts.
- (12) Carbachol.
- (13) Carbinoxamine.
- (14) Chloral hydrate.
- (15) Chlorcyclizine.
- (16) Chloroform.
- (17) Chlorpheniramine.
- (18) Codeine.
- (19) Curare,
- (20) Cyclizine.
- (21) Deltamethrin.
- (22) Dextromethorphan; its salts.
- (23) Diazepam.
- (24) Digitalis, glycosides of; other active principles of digitalis.
- (25) Diphenhydramine.
- (26) Disulfiram.
- (27) Doxylamine.
- (28) Dyflos,
- (29) Emetine.
- (30) Emetine; its salts.
- (31) Ergonine
- (32) Fipronil

- (33) Formaldehyde.
- (34) Formic Acid.
- (35) Glyceryl trinitrate.
- (36) Halogenated Salicylanides and Nitrophenols
- (37) Hormones.
- (38) Hydrochloric acid.
- (39) Hydroxypethidine; its salts.
- (40) Hyoscine.
- (41) Hyoscyamine.
- (42) Imidacloprid
- (43) Imidazothiozoles,
- (44) Imipramine.
- (45) Indomethacin; its salts.
- (46) Insulin.
- (47) Macrocyclic lactones
- (48) Meclozine.
- (49) Mercaptopurine; its salts; derivatives of mercaptopurine; their salts.
- (50) Mercury and its compound.
- (51) Meprobamate.
- (52) Metallic oxalates, other than potassium quadroxalate, if in the form of photographic solutions.
- (53) Monofluoroacetic
- (54) Nitric acid.
- (55) Phenamidine; its salts.
- (56) Phenbutazone.
- (57) Phenindamine.
- (58) Pheniramine.
- (59) Phenols.
- (60) Phenothiazine.
- (61) Phenylbutazone.

(62) Phenylene diamines; toluene diamines; other alkylated-benzenediamines; their salts.

(63) Pholcodine; its salts.

(64) Phosphorous compounds,

(65) Potassium quadroxalate

(66) Potassium permanganate

(67) Praziquantel

(68) Promethazine.

(69) Quinethazone

(70) Quinapyramine.

(71) Quinuronium.

(72) Sodium hydroxide.

(73) Sodium nitrite.

(74) Sulphonamides,

(75) Sulphonamides, parenteral.

(76) Sulphuric acid.

(77) Tripelenamine

(78) Vaccines, administered by a veterinary surgeon or veterinary paraprofessional

(79) Yohimbine.

(80) Zinc Phosphide.

(81) Any other veterinary medicine relevant in the category

CATEGORY III – Authorized Veterinary Medicines –General Sales List (AVM-GSL)

(1) Amitraz

(2) Benzimidazoles, oral preparation of

(3) Carbamates

(4) Creosot obtained from wood.

(5) Croton, oil of.

(6) Dyflos, except the preparations in Part 2

(7) Ecothiopate.

(8) Febantel

- (9) Fluoroacetamide.
- (10) Fluoroacetanilide.
- (11) Guanidines,
- (12) Hydroxy-N-N-dimethyltryptamines, esters or ethers of these; salts of any of the foregoing.
- (13) Imidazothiozoles, oral preparation of
- (14) Mephesisin; its esters.
- (15) Monofluoroacetic except the preparation in Part 2
- (16) Organophosphate
- (17) Oxantel
- (18) p-Amino-salicylic acid; its salts; any preparation of p-Amino salicylic acid; its salts.
- (19) Piperidine.
- (20) polymethylene diguanidines; di-p-anisyl-p-phenetylguanidine.
- (21) Praziquantel oral preparation
- (22) Pyrantel
- (23) Pyrethrins
- (24) Pyrethroids
- (25) Sulphonamides, oral and topical preparations.
- (26) Thallium,
- (27) Toxaphene.
- (28) Tanning chemicals
- (29) Any other veterinary medicine relevant in the category

CATEGORY IV- Alternative Veterinary Medicine – General Sales List (AltVM-GSL)

- (1) Anthelmintic preparations
- (2) Anti-inflammatory preparations
- (3) Antibacterial preparations
- (4) Antifungal preparations
- (5) Antispasmodic preparations
- (6) Diuretics

- (7) Cardiotonic agents
- (8) Expectorants
- (9) Sedatives
- (10) Rubefacient preparations
- (11) Laxatives, purgatives and cathartics.
- (12) Biopesticide preparations
- (13) Galactagogue preparations
- (14) Antiprotozoa preparations
- (15) Disinfectants and antiseptics
- (16) Any other veterinary medicine relevant in the category

THIRD SCHEDULE

FORM A

(r.21(2)(a))

**REPUBLIC OF KENYA
VETERINARY MEDICINE DIRECTORATE VETERINARY MEDICINES
PREMISES INSPECTION FORM**

(to be filled in triplicate, one copy to be retained at the inspected premises)

I, the undersigned of (postal address)have today carried out an inspection ofas required by Regulation 18 of the Veterinary Surgeons and Veterinary Para-professionals (Veterinary Medicines Directorate) Regulations.

Identification of premises;

- (1) Name of owner/proprietor.....
- (2) Physical location(specify).....
- (3) Address.....
- (4) Premise Permit No.
- (5) Authorized classes and categories of medicines dispensed

The following findings are reported—

- Location with respect to fire hazards
- Separation from other veterinary operations
- Separation from non-complementary businesses
- Restriction of access to Category I and II veterinary medicine by personnel
- Vermin and insect proofing
- Security and safety measures for veterinary medicine
- Storage conditions
- Descriptions of floors and the walls of the building
- Description of safety cabinets for medicines.....
- Personnel protection equipment used in premises
- Description of size and space for operations
- Description of disposal system for expired veterinary medicines
- Competency of staff
- Identification of hazard areas

Labeling of sections

Labeling of veterinary medicines designated areas.....

Emergency lighting, firefighting equipment and first aid kit(s)

Emergency protocols displayed

Standard operating procedures displayed.....

Records of movement of all veterinary medicines

Sanitary facilities

Other comments

Summary of significant observations

Inspection carried out in presence of:

Name.ID. No.....Position in the

business.....Signature..... Date.....

I have the following recommendations to make

.....

The previous inspection was carried out on

Signature.....

Designation..... Date

For official use

Premise approved/rejected Action taken Signature

Date The Chief Executive Officer, Veterinary Medicines Directorate

FORM B

(r.21(2)(b))

**REPUBLIC OF KENYA
VETERINARY MEDICINE DIRECTORATE
IMPOUNDING OF SUSPECT VETERINARY MEDICINE FORM**

(to be filled in triplicate, and one copy be retained at the inspected premises)

I being a veterinary medicines inspector Registration number.....have today (date)..... impounded the following veterinary medicines fromlocated at..... incounty and registered under.....

No.	Veterinary medicine	Category	Dosage form	Quantity	Reasons

Impounding carried out in presence of: -

Name:.....IDPosition in the business

..... Date:..... Signature

.....

Date.....

FORM C

(r.21(5))

PREMISES LICENSE FOR A WHOLESALE/RETAIL VETERINARY PHARMACY

Serial No

Messrs

.....

Plot Nohas had their premises inspected in accordance with Regulation 21 and is hereby permitted to carry on the business of

..... as provided in Regulation 21(2) of Veterinary Medicines Directorate Regulations.

Date :

Chief Executive Officer Veterinary Medicines Directorate

Note:

- a) No change of premises is permitted without the authority of the Directorate
- b) This registration shall become void upon any change of ownership of the business
- c) Directorate shall be notified immediately the licensee changes

APPLICATION FOR A LICENCE TO MANUFACTURE A VETERINARY PHARMACEUTICAL/VACCINE /PESTICIDES

The Chief Executive Officer,
Veterinary Medicines Directorate,
P.O.Box 66171-00800,
Westlands, Nairobi
Telephone: +254743795395
Email: info@vmd.go.ke

I/We.....of (postal address)..... having a manufacturing site located at /physical addresshereby apply to manufacture for sale the following Veterinary products.....

This /these Veterinary products has/have the following compositionThe manufacture of the above Veterinary products) will be carried out under the direct personal supervision of.....

.....who has the following qualifications

The manufacture of the above Veterinary products will be carried out in compliance with Good Manufacturing Practice .

Submit the following supportive documents
Previous Manufacturing permit
Good manufacturing Practice if any

Date (Signature of applicant)

FORM E

(r.24(2))

APPLICATION FORM FOR GOOD MANUFACTURING PRACTICE INSPECTION FOR VETERINARY MEDICINES MANUFACTURING FACILITIES

The Chief Executive Officer,
Veterinary Medicines Directorate,
P.O.Box 66171-00800,
Westlands, Nairobi
Telephone: +254743795395
Email: info@vmd.go.ke

1. PARTICULARS OF APPLICANT/LICENSE HOLDER

Name _____ Physical
Address _____
Country _____ Telephone _____
Mobile _____ E-mail _____

2. PARTICULARS OF SITE TO BE INSPECTED Name of contact person

_____ Physical Address (if different from 1.
above) _____
Country _____ Tel _____
Mobile _____ E-mail: _____ Note:

Separate application to be filled in for each individual site

3. CONTACT PERSON ON SITE Name of contact

person _____
Tel: _____ Fax: _____ E-
mail: _____

4. AUTHORISED REPRESENTATIVE/AGENT IN KENYA Name of Local Technical

Representative _____
Tel: _____ Mobile: _____
_____ Email: _____

5. TYPE OF VETERINARY MEDICINES Class of veterinary medicines manufactured (Tick where applicable) • Veterinary pharmaceuticals

- Biologicals
- Nutrients
- Equipment and materials
- Alternative medicines
- Poisons

6. Type of inspection (Tick where applicable)

First Inspection
Re – inspection _____ Date of previous inspection _____
Routine- inspection _____
Previous inspection date.....
Other (please specify).....

7. LINES TO BE INSPECTED

DOSAGE FORM Tick where applicable *ACTIVITIES

- Tablets
- Capsules
- Injections
- Oral liquids
- Creams/Ointments/lotions
- Others (specify)

) *Activity means any of the following:

- Formulation (dispensing, mixing, blending)
- Processing (compression, emulsification etc)
- Packing
- Quality Control
- Warehousing (raw material, finished products)

8. REGISTRATION OF PRODUCTS

Have you registered any products in Kenya; or Have you submitted dossier for registration? YES /NO

If YES, list the veterinary medicines applicable. (Attach a separate sheet if needed).....

I hereby certify that the above information is correct and apply for Good Manufacturing Practice inspection of the above-named site(s).

Signature of applicant..... Date.....

Name.....

**REPUBLIC OF KENYA
VETERINARY MEDICINE DIRECTORATE
LICENSE TO MANUFACTURE VETERINARY MEDICINES**

This is to affirm that
.....having a manufacturing site situated at
.....
..... is hereby licensed to manufacture for sale the following veterinary product (s)
.....
.....
..... under the supervision of
.....

At

Date

Chief Executive Officer,
Veterinary Medicines Directorate

Note;

- (a) This license expires on
- (b) Any change of the person under whose direct personal supervision the manufacture is carried on, whether temporary or permanent, must be notified to the registrar immediately.

FORM G

(r.25(6))

REPUBLIC OF KENYA
VETERINARY MEDICINE DIRECTORATE
VETERINARY MEDICINES GOOD MANUFACTURING PRACTICE LICENCE

SERIAL NO Messrs.

..... of

..... Land Registration
No..... has complied with good manufacturing practices and is
hereby licensed to carry out business of veterinary medicine manufacturing as provided in Regulation
8(2) of Veterinary Medicines Directorate Regulations.

Date

Chief Executive Officer,
Veterinary Medicines Directorate.

Note:

(a) This licence expires on 31st December, 20.....

(b) No change of premises is permitted without the authority of the Directorate.

FORM H1**(r.27(1))****APPLICATION FOR REGISTRATION OF A VETERINARY IMMUNOLOGICAL PRODUCT***(To be submitted as one original hard-copy and one electronic copy in MS-Word)*

The Chief Executive Officer,
 Veterinary Medicines Directorate,
 P.O. Box 66171-00800,
 Westlands, Nairobi
 Telephone: +254743795395
 Email: info@vmd.go.ke

1. A Particulars of the Applicant

Name:	
Physical address:	
Postal address:	
Phone:	
Fax:	
e-mail:	

1.B Particulars of the Immunological Veterinary Product

Product name:	
Pack size(s):	
Description of the Immunological Veterinary Product (e.g. inactivated/attenuated / freeze-dried)	
Main indication(s):	

1.C Particulars of the Manufacturer(s) and Activity (Include the contract manufacturing and quality control laboratories)

	Name	Manufacturing plant address	Activity
1			
2			
3			
4			

Attach copies of certification of recognition of manufacturer from competent authority in the country of manufacture.

2. Authorised Local Technical Representative (LTR)

Name of Local Technical Representative	Address of Local Technical Representative

3. Current Registration and Licensing Status

3.1 Registration status in the country of manufacture (attach validated copy of marketing authorisation of Immunological Veterinary Product issued by the appropriate regulatory authority.

3.2 If not registered in the country of origin, provide Certificate of Origin issued by the competent authority in the country of manufacture.

3.3 If the Immunological Veterinary Product has been refused/deferred/cancelled/ withdrawn in any country or territory supply details.

3.4 List of countries where the Immunological Veterinary Product is already registered.

5. Product Composition

Give the composition of the product in terms of units per dose

5.1. Active (immunogenic) ingredients

Name	Quantity per dose	Specification or reference text

5.2. Inactive ingredients (adjuvant/excipients/preservative)

Name	Quantity per dose	Specification or reference text	Reason for inclusion

5.3. Additional Starting materials

Give details of any additional starting materials used in the manufacturing process but not found in the final product.

5.4 Provide Technical Information and Supporting Documentation

Attach in volumes clearly marked as Volume x of y

DECLARATION BY APPLICANT

1. I, the undersigned certify that all the information in this application form and accompanying documentation is correct, complete and true to the best of my knowledge.
2. I further confirm that the information referred to in my application dossier is available for verification during current GMP inspection.
3. I agree that the undersigned has not marketed or advertised this product in Kenya and will follow the Veterinary Medicines Directorate (VMD) requirements for advertisements of medicines
4. I also agree that I am obliged to follow the requirements of the Veterinary Medicines Directorate Regulations.

Name:

Position in the company...

Signature:

Date.....

Official stamp.....

FORM H2**(r.27(1))****APPLICATION FOR REGISTRATION OF A VETERINARY PHARMACEUTICAL***(To be submitted as one original hard-copy and one electronic copy in MS-Word)*

The Chief Executive Officer,
 Veterinary Medicines Directorate,
 P.O. Box 66171-00800,
 Westlands, Nairobi
 Telephone: +254743795395
 Email: info@vmd.go.ke

Application Number		
Date of submission of the dossier		
Name of the 1 st Evaluator		Signature
Name of the 2 nd Evaluator		Signature
Date of 1st evaluation		
Date of 2nd Evaluation		
Number of files received		
<u>CONCLUSION OF THE ASSESSMENT</u> RECOMMENDED <i>(no outstanding issues)</i> QUERY RAISED <i>(Indicate the sections where query is raised)</i> REJECTED <i>(indicate the module(s) that led to the rejection)</i> <i>(Please delete which does not apply)</i>		
TYPE OF APPLICATION -VETERINARY PHARMACEUTICAL PRODUCT		
MODULE 1: ADMINISTRATIVE INFORMATION		
SECTION 1: PARTICULARS OF THE VETERINARY PHARMACEUTICAL		
1.1 Name and address of Applicant		
(Company) Name: Address: Country: Office telephone number: Mobile telephone number: E-Mail:		
1.2	Trade Name of the veterinary pharmaceutical (Proprietary Name)	
1.3	International Non-proprietary Name (INN) of the Active Ingredient (AI)	
1.4	Strength of Active Ingredient (AI) per unit dosage of the veterinary pharmaceutical:	
1.5	Pharmaceutical Dosage form and route of administration	
1.5.1	Pharmaceutical Dosage form of the veterinary pharmaceutical:	
1.5.2	Route(s) of administration (use current list of standard terms - European Pharmacopoeia)	
1.6	Packing/pack size of the veterinary pharmaceutical:	
1.7	Visual description of the veterinary pharmaceutical <i>(Add as many rows as necessary)</i>	

1.8	Proposed shelf life (in months):
1.8.1	Proposed shelf life (after reconstitution or dilution):
1.8.2	Proposed shelf life (after first opening container):
1.8.3	Proposed storage conditions:
1.8.4	Proposed storage conditions after first opening:
1.9	Pharmacotherapeutic group and Anatomical Therapeutic Chemical (ATC) Code
1.9.1	Pharmacotherapeutic group:
1.9.2	ATC Code: <i>(Please use current ATC code)</i>
1.9.3	If no ATC code has been assigned, please indicate if an application for ATC code has been made: <input type="checkbox"/>
1.10	Legal category
1.10.1	Proposed dispensing category/classification: Product is subject to medical prescription or not subject to medical prescription <i>(Please delete which does not apply)</i>
1.10.2	For veterinary medicine subject to veterinary prescription: Controlled veterinary medicine (POM-V category IA) or Prescription Only Medicine, (IB-POM-V) <i>(Please delete which does not apply)</i>
1.10.3	For veterinary medicine <u>not</u> subject to veterinary prescription: The product will be dispensed from Non-pharmacy outlets and pharmacies (if applicable) or Pharmacies only <i>(Please delete which does not apply)</i>
1.11	Country of origin or country of release:
1.12	Marketing Authorisation in the country of origin and other countries. (Attach certificate of veterinary medicine from competent regulatory authority) If not registered, state reasons
<input type="checkbox"/> Authorised Country: Date of authorisation (dd-mm-yyyy): Proprietary name: Authorisation number: <input type="checkbox"/> Refused Country: Date of refusal (dd-mm-yyyy): Reason for Refusal:	
<input type="checkbox"/> Withdrawn (by applicant after authorisation) Country: Date of withdrawal (dd-mm-yyyy): Proprietary name: Reason for withdrawal: <input type="checkbox"/> Suspended/revoked (by competent authority) Country: date of suspension/revocation (dd-mm-yyyy): Reason for suspension/revocation: Proprietary name:	
1.13	Pre-registration analysis of the veterinary pharmaceutical (Attach certificate of analysis from a laboratory recognized by the Directorate)
1.14	Name(s) and complete address (es) of the manufacturer(s)
1.14.1	Name(s) and complete address (es) of the manufacturer(s) of the finished Veterinary medicine, including the final company releasing veterinary if different from the manufacturer. <i>(Add as many rows as necessary)</i>
Name: Company name: Address: Country:	

Office telephone number:
 Mobile telephone number:
 E-Mail:
 If the manufacturer is different to 1.1 above, explain the relationship:

1.14.2 Name(s) and complete address (es) of the manufacturer(s) of the active ingredient(s) (AI)
(Add as many rows as necessary)

Name:
 Company name:
 Address:
 Country:
 Office telephone number:
 Mobile telephone number:
 E-Mail:

1.15 Good Manufacturing Practice (GMP) status of the manufacturer (s) of the veterinary pharmaceutical
(Attach certificate issued by VMD)

1.16 Name and complete address of the market authorization holder or Manufacturer

Name:
 Company name:
 Address:
 Country:
 Office telephone number:
 Mobile telephone number:
 E-Mail:
If the Market Authorization holder is different to 1.1 above, explain and provide evidence for the relationship:

1.17 Name and address of the authorized Local Technical Representative (LTR)

1.18 Summary of Product Characteristics *(Attach)*

1.19 Batch number(s) of the finished veterinary pharmaceutical used in production, validation and stability
(Add as many rows as necessary)

Clinical/bioequivalence studies

Stability studies

Validation/production scale batches

Comments [e.g., batch size, explanation of NA (not applicable) answers]

Composition of clinical, primary stability and validation/ veterinary medicines batches (kg)

Ingredients	Administration Unit		Bioequivalence <batch number>		Primary stability <batch number>		Production <batch number>	
	Mg	%*	Kg	%*	Kg	%*	kg	%*

Core tablet / capsule contents / injections / suspensions, etc. *(Please delete / change which does not apply)*

AI 1

AI 2

AI 3

Please add / delete as many rows as necessary

Excipient 1

Excipient 2								
Excipient 3								
<i>Please add / delete as many rows as necessary</i>								
Subtotal 1								
Purified water/other solvent(s)								
Film coat / capsule shell / printing ink (<i>Please delete / change which does not apply</i>)								
Proprietary film-coating mixture**								
<i>Please add / delete as many rows as necessary</i>								
Subtotal 2								
Grand total								
Purified water/other solvent(s)								
Equivalence of the composition or justified differences	The compositions of the bioequivalence, stability and validation batches are the same and differences are justified. (<i>Please delete / change which does not apply</i>)							
* Each ingredient is expressed as a percentage of the grand total.								
** All components (.....) of the proprietary mixture are described in the compendia								
2.0 TECHNICAL INFORMATION AND SUPPORTING DOCUMENTS								
Attach in volumes clearly marked as Volume x of y								

DECLARATION BY APPLICANT	
	<ol style="list-style-type: none"> 1. I, the undersigned certify that all the information in this application form and accompanying documentation is correct, complete and true to the best of my knowledge. 2. I further confirm that the information referred to in my application dossier is available for verification during current GMP inspection. 3. I agree that the undersigned has not marketed or advertised this product in Kenya and will follow the Veterinary Medicines Directorate (VMD) requirements for advertisements of medicines 4. I also agree that I am obliged to follow the requirements of the Veterinary Medicines Directorate Regulations. <p>Name:</p> <p>Position in the company...</p> <p>Signature:</p> <p>Date.....</p> <p>Official stamp:.....</p>

FORM H3**(r.27(1))****APPLICATION FOR REGISTRATION OF A BIOCIDAL PRODUCT***(To be submitted as one original hard-copy and one electronic copy in MS-Word)*

The Chief Executive Officer,
Veterinary Medicines Directorate,
P.O. Box 66171-00800,
Westlands, Nairobi
Telephone: +254743795395
Email:info@vmd.go.ke

1	PARTICULARS OF THE PRODUCT
1.1	Common name proposed or accepted by ISO and synonyms (usual name, trade name, abbreviation)
1.2	Other Names
1.3	Chemical name (IUPAC and CA nomenclature or other international chemical name(s))
1.4	CAS Number
1.5	Strength of Active Ingredients (AI) per unit dosage
1.6	Molecular and structural formula
1.7	Molecular weight for each active ingredient
1.8	Specification of purity of the active substance as manufactured in g/kg, g/l or % w/w (v/v) as appropriate, providing inclusively the upper and lower limit
1.9	Intended use or indications of the product
1.10	The identity of any impurities and additives including by-products of synthesis, optical isomers, degradation products (if the substance is unstable) un-reacted and end-groups etc. of polymers and un-reacted starting materials of UVC-substances
1.11	Instructions for use
1.12	Proposed shelf life, shelf life after opening of container and shelf life after reconstitution (Attach stability data)
1.13	Country of origin and release (Attach a registration certificate or authorization to market the product as nutrient and borderline products in the country of manufacture and in other countries)

1.14	Brief description of the physical characteristics of the product (color, size, shape and other relevant features)
1.15	Type of materials for the packaging/container (Attach specifications of the primary container and artworks for labelling and or information leaflets)
1.16	Type of closure system for package or container
1.17	Packaging unit(s)/Pack sizes intended for marketing (Provide 3 samples for every unit)

2. PARTICULARS OF THE APPLICANT (SHOULD BE THE LOCAL TECHNICAL REPRESENTATIVE)	
Name	
Postal Address	
Country	
Physical Address (plot/block No./street/Village/district/region)	
Telephone number	
Email	

Note: If the applicant is not the LTR, explain and provide evidence of the relationship with manufacturer.

3. PARTICULARS OF MANUFACTURER OF FINISHED PRODUCT	
Name	
Postal Address	
Country	
Physical Address (plot/block No./street/Village/district/region)	
Telephone number	
Email	
Good Manufacturing Practice (GMP) status (Attach certificate)	

4	<p>TECHNICAL INFORMATION AND SUPPORTING DOCUMENTATION</p> <p>Attach detailed information in volumes clearly marked as Volume x of y</p>
----------	--

DECLARATION BY APPLICANT	
	<ol style="list-style-type: none"> 1. I, the undersigned certify that all the information in this application form and accompanying documentation is correct, complete and true to the best of my knowledge. 2. I further confirm that the information referred to in my application dossier is available for verification. 3. I agree that the undersigned has not marketed or advertised this product in Kenya and will follow the Veterinary Medicines Directorate (VMD) requirements for advertisements of medicines 4. I also agree that I am obliged to follow the requirements of the Veterinary Medicines Directorate Regulations. <p>Name:</p> <p>Position in the company...</p> <p>Signature:</p> <p>Date:.....</p> <p>Official stamp:.....</p>

FORM H4**(r.27(1))****APPLICATION FOR REGISTRATION OF FEED ADDITIVES***(To be submitted as one original hard-copy and one electronic copy in MS-Word)*

The Chief Executive Officer,
Veterinary Medicines Directorate,
P.O. Box 66171-00800,
Westlands, Nairobi
Telephone: +254743795395
Email: info@vmd.go.ke

1	PARTICULARS OF THE PRODUCT
1.1	Trade Name
1.2	International Non-proprietary Name (INN) of the Active Ingredients (AI)
1.3	Proposed Category
1.4	Strength of Active Ingredients (AI) per unit dosage
1.5	CAS Number
1.6	Other Names
1.7	Molecular formula for each active ingredient
1.8	Molecular weight for each active ingredient
1.9	intended use or indications of the product
1.10	Dosage forms
1.11	Dosages
1.12	Proposed shelf life, shelf life after opening of container and shelf life after reconstitution (Attach stability data)

1.13	Country of origin and release (Attach a registration certificate or authorization to market the product as nutrient and borderline products in the country of manufacture and in other countries)
1.14	Brief description of the physical characteristics of the product (color, size, shape and other relevant features)
1.15	Type of materials for the packaging/container (Attach specifications of the primary container and artworks for labelling and or information leaflets)
1.16	Type of closure system for package or container
1.17	Packaging unit(s) intended for marketing (Provide 3 samples for every unit)

2. PARTICULARS OF THE APPLICANT (SHOULD BE THE LOCAL TECHNICAL REPRESENTATIVE)

Name	
Postal Address	
Country	
Physical Address (plot/block No./street/Village/district/region)	
Telephone number	
Email	

Note: If the applicant is not the LTR, explain and provide evidence of the relationship with manufacturer.

3. PARTICULARS OF MANUFACTURER OF FINISHED PRODUCT

Name	
Postal Address	
Country	
Physical Address (plot/block No./street/Village/district/region)	
Telephone number	
Email	

Good Manufacturing Practice (GMP) status (Attach certificate)	
--	--

4	DETAILS OF THE PROCEDURES INVOLVED IN THE VARIOUS STAGES OF MANUFACTURE (A description of the method of production, manufacturing of the feed additive, the method of analysis of the additive in feed according to its intended use and, where appropriate, of the method of analysis for the determination of the level of residues of the feed additive, or its metabolites, in food from animal origin)
----------	--

5. INGREDIENTS			
No.	Name	Proportion (e.g. %, ppm, units)	Purpose of use

6. ADDITIVES			
No.	Name	Proportion (e.g. %, ppm, units)	Purpose of use

7	RAW MATERIALS SPECIFICATIONS (limits or criteria of acceptance or rejection of raw materials). <i>Attach Certificates of Analysis from an accredited laboratory as proof of conformance to all declared specifications.</i>
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8	FINISHED PRODUCT SPECIFICATIONS (acceptable limits of the physical, chemical, biological and microbiological parameters). <i>Attach Certificates of Analysis from an accredited laboratory as proof of conformance to all declared specifications.</i>
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9	SAFETY AND SAFETY MANAGEMENT INFORMATION (provide references)
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10	PROPOSAL FOR POST MARKETING MONITORING (For additives which do not belong to category of preservatives or oxidants, and for additives containing or produced from GMOs)
-----------	--

DECLARATION BY APPLICANT	
	<ol style="list-style-type: none"> 1. I, the undersigned certify that all the information in this application form and accompanying documentation is correct, complete and true to the best of my knowledge. 2. I further confirm that the information referred to in my application dossier is available for verification. 3. I agree that the undersigned has not marketed or advertised this product in Kenya and will follow the Veterinary Medicines Directorate (VMD) requirements for advertisements of medicines 4. I also agree that I am obliged to follow the requirements of the veterinary medicines directorate regulations. <p>Name:</p> <p>Position in the company...</p> <p>Signature:</p> <p>Date:.....</p> <p>Official stamp:.....</p>

FORM H5**(r.27(1))****APPLICATION FOR REGISTRATION OF A VETERINARY EQUIPMENT/DEVICE***(To be submitted as one original hard-copy and one electronic copy in MS-Word)*

The Chief Executive Officer,
Veterinary Medicines Directorate,
P.O. Box 66171-00800,
Westlands, Nairobi
Telephone: +254743795395
Email: info@vmd.go.ke

1. PARTICULARS OF THE APPLICANT (SHOULD BE THE LOCAL TECHNICAL REPRESENTATIVE)	
Name (Contact Person)	
Postal Address	
Country	
Physical Address (plot/block No./street/Village/district/region)	
Telephone number	
Email	

Note: If the applicant is not the LTR, explain and provide evidence of the relationship with manufacturer.

2. PARTICULARS OF MANUFACTURER	
Name (Contact Person)	
Postal Address	
Country	
Physical Address (plot/block No./street/Village/district/region)	
Telephone number	
Email	
Good Manufacturing Practice (GMP) status (Attach certificate)	

3	SUMMARY OF THE EQUIPMENT/DEVICE
3.1	Classification of the device:
3.2	An overview, e.g., introductory descriptive information on the veterinary device and any novel features
3.3	Commercial marketing history
3.4	Intended uses and indications in labelling
3.5	List of regulatory approval or marketing clearance obtained
3.6	Status of any pending request for market clearance
3.7	Important safety/performance related information
4	RELEVANT ESSENTIAL PRINCIPLES AND METHOD USED TO DEMONSTRATE CONFORMITY
4.1	<p>Identify the general method used to demonstrate conformity to each applicable Essential Principle. The evidence of conformity can be provided in tabular form with supporting documentation attached.</p> <p>Note: The manufacturer of the equipment/device will determine which principles are appropriate for a particular equipment/device while taking into account the intended purpose of the equipment/device.</p>
5	DESCRIPTION OF THE EQUIPMENT/DEVICE
5.1	<p>Detailed description of the equipment/device attributes is necessary to explain how the equipment/device functions, the basic scientific concepts that form the fundamentals for the equipment/device, the component materials and accessories used in its principles of operation as well as packaging.</p> <p>A complete description of each functional component, material or ingredient of the equipment/device should be provided, with labelled pictorial representation of the equipment/device in the form of diagrams, photographs or drawings, as appropriate.</p>
5.2	Intended use according to the data supplied by the manufacturer in the instructions as well as the functional capability of the equipment/device.

5.3	Instructions of use according to information from the manufacturer including the procedures, methods, frequency, duration, quantity and preparation to be followed for safe use of the veterinary equipment/device.
5.4	Description of the disease or condition and the population for which the equipment/device should not be used for the purpose of diagnosis or treatment
5.5	Specific hazard alert information that a user needs to know before using the equipment/device
5.6	Special care necessary for the safe and effective use of the equipment/ device.
5.7	Chemical, biological and physical characterization of materials that have direct or indirect contact with the animal body.
5.8	The functional characteristics and technical performance specifications for the Equipment/device including, as relevant, accuracy, sensitivity, specificity of measuring and diagnostic veterinary equipment/ devices, reliability and other factors; and other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging to the extent necessary to demonstrate conformity with the relevant Essential Principles
6	VERIFICATION AND VALIDATION DOCUMENTS (To be attached): Data from pre-clinical and clinical studies
7	EQUIPMENT/DEVICE LABELLING
7.1	Labels on the equipment/device and its packaging, Instructions for use/user's manual
7.2	Samples of Labels on the veterinary equipment/ device and its Packaging
7.3	Results of the risk analysis based upon international or other recognized standards
8	SUMMARY OR REFERENCES OF THE MANUFACTURING PROCESSES, INCLUDING QUALITY ASSURANCE MEASURES

DECLARATION BY APPLICANT

1. I, the undersigned certify that all the information in this application form and accompanying documentation is correct, complete and true to the best of my knowledge.
2. I further confirm that the information referred to in my application dossier is available for verification.
3. I agree that the undersigned has not marketed or advertised this product in Kenya and will follow the Veterinary Medicines Directorate (VMD) requirements for advertisements of medicines
4. I also agree that I am obliged to follow the requirements of the veterinary medicines directorate regulations.

Name:

Position in the company...

	<p>Signature:</p> <p>Date:.....</p> <p>Official stamp:.....</p>
--	---

FORM I**(r.27(1))****APPLICATION FOR REGISTRATION OF A VETERINARY PESTICIDE***(To be submitted as one original hard-copy and one electronic copy in MS-Word)*

The Chief Executive Officer,
Veterinary Medicines Directorate,
P.O. Box 66171-00800,
Westlands, Nairobi
Telephone: +254743795395
Email: info@vmd.go.ke

<i>Dossier Reception: For VMD Use Only</i>	
Application Number	Number of files received:
Date of submission of the dossier:	
Name of the 1 st Evaluator	Signature
Name of the 2 nd Evaluator	Signature
Date of 1 st Evaluation	
Date of 2 nd Evaluation	
CONCLUSION OF THE ASSESSMENT: RECOMMENDED <i>(no outstanding issues;</i> QUERY RAISED <i>(Indicate the sections where query is raised);</i> REJECTED <i>(indicate the part(s) that led to the rejection) (Indicate appropriately)</i>	

<i>Applicant use only</i>	
PART 1: ADMINISTRATIVE INFORMATION	
Name of the Applicant:	
Status: Manufacturer Formulator Others (specify)	
Business registration Number	
Address & Physical Location:	Office telephone Number:
E mail:	Mobile Telephone Number
Website:	
1.1 Local Agent	
Status: Manufacturer Formulator Others (specify)	
Business registration Number	
Address & Physical Location:	Office telephone Number:
E mail:	Mobile Telephone Number
1.2 Product Trade Name (Brand Name):	
1.2.1 Trade Mark Holder	
1.2.2 Type of formulation	Others (indicate)
<i>Applicant use only</i>	
PART 1: ADMINISTRATIVE INFORMATION	

1.2.3	Common name of the Active ingredient (s)	
1.2.4	Strength of the active Ingredient (s)	
1.2.5	Packaging/pack size of the Veterinary Pesticide	
1.2.6	Visual description of the Veterinary pesticide	
1.2.7	Proposed shelf life and storage conditions	
1.2.8	Proposed shelf life after first opening and storage conditions	
1.2.9	Patent Status and expiry date	
1.2.10	Target animal(s)	
1.2.11	Target parasites/vectors	
1.2.12	Number and frequency of application	
1.2.13	Target animal safety	
1.2.14	Withholding period and Maximum residue limits	

<i>Applicant use only</i>	
PART 1: ADMINISTRATIVE INFORMATION	

1.3 Marketing Authorisation in the country of origin and other countries. (Attach certificate of registration of the veterinary pesticide from competent regulatory authority) **If not registered, state reasons**

Authorised

Refused

Country

Country

Date of Authorization

Date of Refusal

Proprietary name:

Reason for refusal:

Authorization No.

Withdrawn (by applicant after authorization)

Suspended/Revoked (by the Competent authority)

Country:

Country:

Date of withdrawal:

Date of Suspension/Revocation: Reason of

Reason for withdrawal

Suspension/Revocation:

1.3.1 Country of Origin or Country of release

1.4 Pre-registration analysis of the Veterinary pesticide (Attach certificate of analysis from Institution(s) recognized by the Veterinary Medicines Directorate)
 Provided

Not Provided

1.5 Name(s) and complete address (es) of the manufacturer(s)

Applicant use only

PART 1: ADMINISTRATIVE INFORMATION

1.5.1 Name(s) and complete address (es) of the manufacturer(s) of the finished Veterinary medicine, including the final company releasing veterinary if different from the manufacturer.

1.5.2 **Name(s) and complete address (es) of the manufacturer(s) of the technical grade active ingredient(s) (TGAI(s))**

1.5.3 **Good Manufacturing Practice (GMP) status of the manufacturer (s) of the veterinary pesticide**
Provided Not provided Reason

1.5.4 **Summary of Dossier (Attach)**

TECHNICAL INFORMATION AND SUPPORTING DOCUMENTS
Attach in volumes clearly marked as Volume x of y.

DECLARATION BY APPLICANT

- 5. I, the undersigned certify that all the information in this application form and accompanying documentation is correct, complete and true to the best of my knowledge.
- 6. I further confirm that the information referred to in my application dossier is available for verification during current GMP inspection.
- 7. I agree that the undersigned has not marketed or advertised this product in Kenya and will follow the Veterinary Medicines Directorate (VMD) requirements for advertisements of medicines
- 8. I also agree that I am obliged to follow the requirements of the veterinary medicines directorate regulations.

Name:

Position in the company...

Signature:

Date:.....

Official stamp:.....

REPUBLIC OF KENYA
VETERINARY MEDICINE DIRECTORATE
PROVISIONAL CERTIFICATE OF REGISTRATION OF VETERINARY MEDICINE
(Valid for a maximum of 3 months)
Registration Number

It is hereby certified that the veterinary medicine as described hereunder has been registered subject to the conditions indicated below:

1. Trade name under which marketed
2. Approved name (in pharmacopoeia)
.....
3. Form of preparation
4. Active ingredient(s) and strength(s)
5. Condition(s) under which veterinary medicine is registered
.....
6. Name and business address of manufacturer.....
7. Registered in the name of Business address
.....
8. Name and Business Address of the Local Technical Representative
9. Date of registration
10. Expiry date of registration.....
11. Date

Registrar of Veterinary Medicines
Veterinary Medicines Directorate

REPUBLIC OF KENYA
VETERINARY MEDICINE DIRECTORATE
CERTIFICATE OF REGISTRATION OF VETERINARY MEDICINE
Registration Number

.....

It is hereby certified that the veterinary medicine as described hereunder has been registered subject to the conditions indicated below:

- 1. Trade name under which marketed.....
- 2. Approved name (name in pharmacopoeia)
- 3. Form of preparation
- 4. Active ingredient(s) and strength(s)
- 5. Condition(s) under which medicine is registered
-
- 6. Name and business address of manufacturer
-
- 7. Registered in the name of (MAH)..... Business address
- 8. Name and Business Address of the Local Technical Representative.....
- 9. Date of registration
- 10. Expiry date of registration
- 11. Date

Registrar of Veterinary Medicines
Veterinary Medicines Directorate

**APPLICATION FOR RENEWAL OF REGISTRATION OF A VETERINARY
MEDICINE**

(To be submitted as one original hard-copy and one electronic copy in MS-Word)

The Chief Executive Officer,
 Veterinary Medicines Directorate,
 P.O.Box 66171-00800,
 Westlands, Nairobi
 Telephone: +254743795395
 Email: info@vmd.go.ke

Date (dd/mm/yyyy)	
Name & Address of applicant	
Trade Name of Product	
INN of Active Ingredients and Strength	
Dosage Form	
Manufacturer	
MAH Name	
LTR Name	
VMD Registration Number	
VMD classification (LN. No. 29 of 2022 Schedule 2 Part I)	
Date of registration (attach registration certificate)	
GMP status (attach GMP certificate)	
Changes to the product since registration	
Pharmacovigilance report	
Payment (Attach a copy of payment receipt)	

DECLARATION BY APPLICANT

1. I, the undersigned certify that all the information in this application form and accompanying documentation is correct, complete and true to the best of my knowledge.

Name:

	Position in the company..... Signature: Date:..... Official stamp:.....
--	--

FOR OFFICIAL USE	
Findings of pharmaco-vigilance and other findings	
Recommendations: Approved/suspended/rejected (give reasons)	

Name

Signature..... Date

CEO, VMD

**APPLICATION FOR RETENTION OF A VETERINARY
MEDICINE IN THE REGISTER**

(To be submitted as one original hard-copy and one electronic copy in MS-Word)

The Chief Executive Officer,
Veterinary Medicines Directorate,
P.O.Box 66171-00800,
Westlands, Nairobi
Telephone: +254743795395
Email: info@vmd.go.ke

Date (dd/mm/yyyy)	
Name & Address of applicant	
Trade Name of Product	
INN of Active Ingredients and Strength	
Dosage Form	
Manufacturer	
MAH Name	
LTR Name	
VMD Registration Number	
VMD classification (LN. No. 29 of 2022 Schedule 2 Part I)	
Retention Year (attach retention certificate of previous year)	
GMP status (attach GMP certificate)	
Changes to the product since registration or previous retention	
Payment (Attach a copy of payment receipt)	

DECLARATION BY APPLICANT

	<p>1. I, the undersigned certify that all the information in this application form and accompanying documentation is correct, complete and true to the best of my knowledge.</p> <p>Name:</p> <p>Position in the company.....</p>
--	---

	Signature: Date:..... Official stamp:.....
--	--

FOR OFFICIAL USE	
Findings of pharmaco-vigilance and other findings	
Recommendations: Approved/suspended/rejected (give reasons)	

Name

Signature..... Date

CEO, VMD

APPLICATION FOR DESIGNATION TO CONDUCT A CLINICAL OR NON CLINICAL TRIAL

PART 1: ADMINISTRATIVE DETAILS

- 1.1 Applicant
- 1.2 Address
- 1.3 Contact Person (Address, Telephone Number, E-mail Address)

PART 2: DETAILS OF TRIAL

- 2.1 Details of Site(s) (Name of site, physical address, contact details, contact person)
- 2.2 Details of investigators and staff (Investigators, staff, number of staff, names, qualifications, experience preferably in a table and include the titles of investigators involved)
- 2.3 Details of capacity
(site facilities, equipment, emergency facilities, other relevant infrastructure and work load documents)
- 2.4 Details and evidence of competence of the laboratories:
 - Collection and processing of samples for shipping to centralised testing facilities (include conditions of shipping)
 - Bedside/point-of-contact testing and details of training of staff
 - Screening and safety testing of samples during the trial
 - Specialised end-point testing

DECLARATION BY APPLICANT

1. I, the undersigned certify that all the information in this application form and accompanying documentation is correct, complete and true to the best of my knowledge.

Name:

Position in the company.....

Signature:

Date:.....

Official stamp:.....

VETERINARY PHARMACOVIGILANCE

**REPORT FOR SUSPECTED ADVERSE REACTIONS IN ANIMALS OR IN HUMANS
AFTER THE USE OF A VETERINARY MEDICINE**

	Sender report identification-case ref. No:	Page
Safety issues in animals <input type="checkbox"/> in humans <input type="checkbox"/> Lack of expected efficacy <input type="checkbox"/> Withdrawal period issues <input type="checkbox"/> Environmental problem issues <input type="checkbox"/>	Reporting county: Purchase county: Report source:	
1. Address of competent authority	2. Name and address of sender	
Date complaint received by sender: (dd-Mon-yyyy) Type of report <input type="checkbox"/> initial <input type="checkbox"/> follow up (date, case number) Person who reported the reaction: Veterinarian <input type="checkbox"/> Owner <input type="checkbox"/> Physician <input type="checkbox"/> Pharmacist <input type="checkbox"/> Other		
3. VETERINARIAN/PHARMACIST/PHYSICIAN Name: Address: Telephone no:	4. ANIMAL OWNER/HUMAN PATIENT Name: Address: Telephone no:	
5. ANIMAL DATA No. of animals treated: No. of animals showing signs: No. of animals died: Animal characteristics (animal(s) showing signs) Species: Breed/production type:		

Were the unexpected signs treated? If yes, give details of treatment including product(s) used:

Reaction data continued;
Outcome of reaction to date:

	Killed/ euthanise d	Died	Under treatment	Alive with sequelae	Recover ed	Unknown
No. of animals:						
Date when:						

8. ATTENDING VETERINARIAN'S LEVEL OF SUSPICION THAT DRUG CAUSED

Possible Unlikely No attending vet

9. PREVIOUS EXPOSURE AND REACTION(S) TO PRODUCTS

Previous exposure to the suspect product? No Yes Date:
Previous reaction to the suspect product? No Yes Describe:
De-challenge information:

10. DETAILS OF SUSPECTED ADVERSE REACTION(S) IN HUMANS

Patient details: Sex: Pregnant Age/date of birth:
Occupation (if relevant):
Date of exposure:
Nature and duration of exposure, reaction details (including symptoms) and outcome:

11. CASUALTY ASSESSMENT

Classification: A(probable) B(possible) O(unclassified)

O1(inconclusive) N(unlikely)

Reasons for classification:

FOR COMPETENT AUTHORITY USE ONLY

Name and title of person responsible for the accuracy of the information

Signature

Date

Attachments included:

Reports to follow:

Form O

r.39

Application form for variation to veterinary immunological or veterinary pharmaceutical product(s)

1. Trade name:

1.1 Name of the immunological/pharmaceutical product (s)

1.2 Main indication

Species:

Disease:

2. Dosage form:

3. Registration number and date of approval:

6. Type of change(s) (State which type of Variation):

6.1 Other Application(s) (Please provide brief information on any ongoing variation or other variation(s) submitted in parallel, or renewal application(s), or line-extension(s)):

6.2. Scope (Please specify scope of the change(s) in a concise way):

6.3 Background for change & Justification for Consequential change(s) Please give brief background explanation for the proposed change(s) to your marketing authorization as well as a justification in case of consequential change(s):

6.4 Present

(Please specify precise present wording or specification)

Proposed

(Please specify precise proposed wording or specification)

In the case of changes to the Summary of Product Characteristics and/or package leaflet, enclose a copy of the current SPC clearly marked to show the differences (new text and deleted text) between the proposed new version and the current text, previous version or reference text.

7. Technical Information and Supporting Documentation

Provide all technical information and documentations to support the variation(s).

8. Details of applicant (Must be the holder of the marketing authorization/registration certificate)

Name:

Business Address:

Postal Address:

Country:

Phone:

Email:

Declaration of the Applicant:

I hereby submit an application for the above Marketing Authorization to be varied in accordance with the proposals given above.

I declare that (Please tick the appropriate declarations):

- There are no other changes than those identified in this application (except for those addressed in other variations submitted in parallel; such parallel variations have to be specified under 'Other Application(s)');
- Where applicable, Variation fees have been paid;
- Change will be implemented from: Next production run/next printing

Name:

Qualification:

Position in the company:

Signature:

Date:

Official stamp:

FORM P**(r. 46(2))****REGISTER OF APPROVED VETERINARY PHARMACY PREMISES**

S/No of Permit	Type of Veterinary Pharmacy	Physical Location	Name of Business	Reg. No. of Business	Name & Contact of Proprietor	Name, Contact & Qualification of Professional In- Charge	Date of Permit

APPLICATION FOR A PREMISES LICENSE FOR A RETAIL VETERINARY PHARMACY

The Chief Executive Officer,
Veterinary Medicines Directorate,
P.O.Box 66171-00800,
Westlands, Nairobi
Telephone: +254743795395
Email: info@vmd.go.ke

1. Applicant Details

Applicant's Name: Professional Reg. No..... Email
address:..... Cell Phone No..... ID/Passport/Alien ID
No:..... Nationality..... Premise Name &
Address:.....
Qualification Period of
experience working in a veterinary pharmacy years.

2. Premise Location:

County:..... Town:.....
Road:..... Building:.....

3. Proposed category of vet medicine that will be traded in:

4. Other professionals working in this premise (add new columns as necessary)

No.	Names	Professional registration No.	qualification and experience
1			
2			

DateSignature of the Applicant

Note: all fields are MANDATORY. Attach a copy of previous premise license, if any, a copy of current registration with the professional regulator and the business registration details where applicable. Non-Kenyans to attach current work permit. Incomplete forms will not be processed.

APPLICATION FOR A VETERINARY WHOLESALE DEALERS PREMISES LICENSE

The Chief Executive Officer,
Veterinary Medicines Directorate,
P.O.Box 66171-00800,
Westlands, Nairobi
Telephone: +254743795395
Email: info@vmd.go.ke

1. Applicant's details: Applicants name.....Professional Reg.
No..... Business Name:Business Reg. No.
..... Email address:.....Cell Phone
No..... ID/Passport/Alien ID No:.....
Nationality..... Premise Name & Address:.....
..... Premise Location:.....
..... County:.....
.....
Town:.....
Road:..... Building:.....
.....

2. Supervising Veterinary Surgeon Name.....Professional Reg.
No..... Email address:.....Cell Phone
No..... ID/Passport/Alien ID
No:.....Nationality.....

3. Other professionals working in this
premise. No. Names Position in the business Qualification Registration / enrollment no. 1. 2. 3. 4. Kenya
Subsidiary Legislation, 2015 1413 5. 6. 7. 8. Signature of the ApplicantDate

..... Note: all fields are MANDATORY. Attach a certified copy of
certificate of registration /incorporation of the business and memorandum and articles of incorporation,
previous premise license, a copy of current registration with the professional regulator and the business
registration details where applicable. Non-Kenyans to attach current work permit. Incomplete forms will
not be processed. -----

FORM R1

(r.47(5))

REPUBLIC OF KENYA
VETERINARY MEDICINE DIRECTORATE LICENSE FOR A RETAIL VETERINARY
PHARMACY

SERIAL NO

Messrs.

of

Plot No..... is permitted to carry on business of retail veterinary pharmacy as provided in Regulation 22(4) of Veterinary Medicines Directorate Regulations.

This license allows trade in veterinary medicines in category

Date Chief Executive Officer, Veterinary Medicines Directorate.

Note:

- (a) This registration expires on 31st December, 20.....
- (b) No change of premises is permitted without the authority of the Directorate.
- (c) This registration shall become void immediately upon any change of ownership of the business.
- (d) Directorate shall be notified immediately the licensee changes

**REPUBLIC OF KENYA
THE VETERINARY MEDICINE DIRECTORATE
VETERINARY WHOLESALE DEALERS PHARMACY LICENSE**

SERIAL NO

Messrs. of

Plot No..... is permitted to carry on business of veterinary medicines wholesaling as provided in Regulation 22(4) of Veterinary Medicines Directorate Regulations.

The business shall be under the supervision ofKVB Reg.

No.....(where applicable)

Date

Chief Executive Officer,
Veterinary Medicines Directorate.

Note:

(a) This registration expires on 31st December, 20.....

(b) No change of premises is permitted without the authority of the Directorate.

(c) This registration shall become void immediately upon any change of the supervisor of the business and may resume practice when a new supervisor has been approved by the Council and brought on board.

(d) Directorate must be notified immediately the licensee changes.

FORM S

(r.53(2))

APPLICATION FOR IMPORT/ EXPORT PERMIT FOR A VETERINARY MEDICINE

The Chief Executive Officer,
Veterinary Medicines Directorate,
P.O.Box 66171-00800,
Westlands, Nairobi
Telephone: +254743795395
Email: info@vmd.go.ke

Application No.....
Date.....

Part I

Name of Importer/Exporter.....
Address.....

Tel. No.....Business Location..... Land
Reg.NO.....Street/Road.....Town..... PIN
NO.....

VAT NO..... Commodity..... Value (FOB)
Kshs..... QuantityDate of Manufacture.....Expiry
Date.....

Purpose of Importation/Exportation.....

Country of Origin..... Destination..... Last Imports/Exports
Quantity Value Kshs.....
Date.....

Note:

Part I to be completed by the applicant. Misleading information in Part I may lead to invalidation of the application and/or prosecution.

Part II. EVALUATION BY VETERINARY MEDICINES DIRECTORATE (VMD)

(a) The Directorate has evaluated the product.....and confirms that it is
registered/not registered forunder
Reg.No.....
OR for Experimental/ Raw materials(delete as appropriate)

(b) recommended/ not recommended for importation/exportation

Reasons:

- 1.
- 2.
- 3.

Evaluating Officer

Name:.....

Signature:.....

CHIEF EXECUTIVE OFFICER: Approved/Not Approved

Name..... Signed

.....Date

Valid for Three Months, from the date of approval, for one consignment only

REPUBLIC OF KENYA
VETERINARY MEDICINE DIRECTORATE
PERMIT FOR IMPORTATION/ EXPORTATION OF A VETERINARY MEDICINE

Permit No.....
Application No
This permit is granted to
To import/export a veterinary medicine(s)
Trade name
Registration number
Date of expiry of registration
Registered uses
Country of origin (if being imported)
Country of destination (if being exported)
Harmonisation Code (HS) Code
Approved common name
Chemical name
Formulation type
Concentration (A.I. %)
State of veterinary medicine (Tick appropriately) A.I. or Formulated.....
Category of veterinary medicine.....
Purpose of import/export
Registered use
Quantity authorized for importation or exportation
Date
Chief Executive Officer Name

Signature..... Stamp and Seal Fee paid
Date Receipt No.

Note:

- 1. This permit is not transferable to any other person without the approval of the Directorate.
2. This permit is valid for one consignment only, for three (3) months from the date of issue.

APPLICATION FOR VETERINARY MEDICINE ADVERTISEMENT

The Chief Executive Officer,
Veterinary Medicines Directorate,
P.O. Box 66171-00800,
Westlands, Nairobi
Telephone: +254743795395

Email: info@vmd.go.ke

Applicant's details:

Applicant's name.....
Wholesale Dealer's No.....
Location.....
Email address.....
Cell Phone No.....
Superintending Vet.....

Product Details:

Product Name.....
Registration No.....
Country of Manufacture.....
Category.....
Formulation.....
Uses.....
Target Audience.....
Form of Advertisement.....

Evaluation by the VMD

The application is Approved [] Not Approved []

If not approved state reason(s) below:

.....
.....

Note:

- 1. A sample of the envisaged advertisement should be submitted together with the application
2. Advertising is any activity that is aimed or designed to promote the sale, supply or use of a veterinary medicine, whether they are for profit or not and includes electronic advertising. Price lists should not be included;
3. Medicines shall be advertised for the authorised uses only;
4. Advertisements shall not be misleading;

5. Advertisements shall be in accordance with guidelines;
6. Advertisement of antibiotics should not encourage unnecessary use of these medicines and all advertising material should contain a caption indicating that the prescription and use of the medicine should be in accordance with the responsible use of antibiotics.
7. The following Veterinary medicines shall not be advertised:
 - Medicines available on prescription to the general public,
 - Medicines that are not authorised for use in Kenya.

LICENSE TO ADVERTISE A VETERINARY MEDICINE

License No

This license is granted to

Authorization for the advertisement of

Registration No. To the
following categories of audiences

Special provisions.....

Fees paid

This permit is valid upto

Date

Chief Executive Officer,

Veterinary Medicines Directorate

FOURTH SCHEDULE

r(24,28,29,34,53)

FEES

	Purpose	Fees (Non-refundable)	Frequency
1	Application forms under these regulations shall be issued free of charge		
2	Inspection fee: (i) Retail Veterinary Pharmacy	Kshs 15,000	Once
3	Inspection fee: (ii) Wholesale Veterinary Pharmacy	Kshs 30,000	Once
4	Good Manufacturing Practice inspection per site		
5	1) Local manufacturing site.	Kshs 100,000	Every three (3) years
6	2) Foreign manufacturing site	USD 4,000	Every three (3) years
7	Registration fees per imported veterinary pharmaceutical, veterinary Immunological, veterinary pesticide or Alternative Medicine	USD 1,000	Once
8	Registration fees per locally manufactured veterinary pharmaceutical, veterinary Immunological, veterinary pesticide or Alternative Medicine	USD 500	Once
9	Registration fees per imported Feed Additive, Biocidal product or Equipment/Device	USD 100	Once
10	Registration fees per locally manufactured Feed Additive, Biocidal product or veterinary equipment/device	USD 50	Once
11	Appeals for rejected application for registration of veterinary medicine	USD 300	Per Application
12	Retention of a veterinary pharmaceutical, veterinary immunological, veterinary pesticide and Alternative Medicine in the register	USD 300	Annually
13	Retention of a feed additive, biocidal product and Equipment/device products in the register	USD 30	Annually
14	Veterinary pharmacy fee:		
	1) Wholesale	Kshs 30,000	Annual
	2) Retail	Kshs 10,000	Annual
15	Manufacturer fee	Kshs 30,000	Annual
16	Import permit	Kshs 1,000	Per consignment
17	Inspection/verification fee	1% of the consignment value with 0.25% to be paid as levy to veterinary pharmaceutical industry for product	Per FOB consignment

		stewardship activities	
18	Supervision fee for Disposal of expired, damaged, illegal veterinary medicines and packaging materials	Ksh 5,000	Per inspection
19	Advertisement per veterinary medicine	Kshs 50,000	Annual
20	Fees for duplicate certificate of registration, permit or license	Kshs 1,000	Per copy