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THE VETERINARY SURGEONS AND VETERINARY PARAPROFESSIONALS ACT, 2011

(*No.* 29 *of* 2011)

THE VETERINARY SURGEONS AND VETERINARY PARAPROFESSIONALS ACT (THE VETERINARY MEDICINES DIRECTORATE) REGULATIONS, 2015

Regulation

PART I—PRELIMINARY

THE VETERINARY SURGEONS AND VETERINARY PARAPROFESSIONALS ACT, 2011

(*No.* 29 *of* 2011)

IN EXERCISE of the powers conferred by section 6 (2) (f) of the Veterinary Surgeons and Veterinary Para-professionals Act, 2011, the Kenya Veterinary Board makes the following regulations:—

THE VETERINARY SURGEONS AND VETERINARY PARAPROFESSIONALS (THE VETERINARY MEDICINES DIRECTORATE) REGULATIONS, 2015

PART I—PRELIMINARY

Citation

1. These Regulations may be cited as the Veterinary Surgeons and Veterinary Paraprofessionals (Veterinary Medicines Directorate) Regulations, 2015.

Interpretation

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

"accredited laboratory" means a laboratory recognized as an accredited laboratory by the Directorate;

"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 commonly used in traditional animal treatments;

"Cabinet Secretary" means the Cabinet Secretary responsible for matters relating to veterinary services;

"Chief Executive Officer" means the Chief Executive Officer of the Directorate appointed under regulation 13;

"Committee" means the Veterinary Medicines Registration Committee established under regulation 27;

"controlled veterinary medicine" means a veterinary medicine specified in the Fourth Schedule as a Category I or Category II of veterinary medicine;

"Conventional medicines" means the regular and standardized veterinary medicines;

"Council" means the Council of the Directorate comprised under regulation 8 (1);

"crude drug" means an unrefined medicine of biological origin;

"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;

"inspector" means a person appointed as an inspector under regulation 45;

"manufacture" means any stage in the manufacturing of a veterinary medicine until the finished product is ready for sale in its final form as specified in the marketing 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;

"market authorization" means registration of a veterinary medicine by the Council and the issuance of a registration certificate under regulation 23;

"orphan veterinary medicine" means a veterinary medicine that is not economical to trade in but is required for specific medical use;

"pharmaco-vigilance" means the routine inspections and surveys carried out in the veterinary medicines market to safeguard general animal and human health and trade;

"quality assurance standards" means the good manufacturing practice, good laboratory practice, good veterinary practice or any other standard developed by an international standardization body, the East African Community Standards Committee or the Kenya Bureau of 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;

"register" means a register maintained by the Council containing the details of—

(a) premises which have been issued with a permit in accordance with these Regulations; or

(b) veterinary medicines registered in the country;

"retailer" means a veterinary pharmacy registered by the Council for the sale of veterinary medicines to the end users;

"specialized committees" means persons who are not Council members;

"veterinary medicines inspector" means an inspector appointed by the Council pursuant to regulation 45;

"veterinary pesticide" means a veterinary medicine used as a pest control product on animals or the animals' environment;

"veterinary pharmaceutical" means a chemical substance formulated or compounded as a single active ingredient or in any combination of the chemical substances, for veterinary curative use;

"veterinary pharmacy" means a business authorized by the Council to stock, dispense or distribute veterinary medicines for sale;

"veterinary pharmacy assistant" means a veterinary para-professional trading in veterinary medicines listed under Category III of the Fourth Schedule;

"veterinary pharmacy practice" means the business of veterinary pharmacy carried out by veterinary surgeons, veterinary para-professionals or any other person permitted by the Council to carry out veterinary pharmacy practice ;

"veterinary product" means veterinary medicines and veterinary pesticides;

"wholesaler" means a manufacturer or veterinary pharmacy approved by the Council to trade in bulk in the supply of veterinary medicines to wholesalers or retailers in the original outer pack-sizes.

Objectives and purpose of the Regulations.

3. The object and purpose of these Regulations is to—

(a) regulate the manufacture, importation, exportation, registration, distribution, prescription and dispensing of veterinary medicines and the practice of veterinary pharmacy in Kenya; and

(b) advise the Kenya Veterinary Board in relation to all aspects listed under paragraph (a).

Application.

4. Subject to regulation 58, these Regulations shall apply to all conventional and alternate veterinary medicine.

PART II —THE VETERINARY MEDICINES DIRECTORATE

Establishment of the Directorate.

5. (1) There is hereby established a Directorate to be known as the Veterinary Medicines Directorate whose management shall vest on a Council appointed under regulation 8.

(2) The Directorate shall be a body corporate with perpetual succession and a common seal and shall in its corporate name be capable of—

(a) suing and being sued;

(b) taking, purchasing, or otherwise acquiring, holding, charging or disposing of movable and immovable property;

(c) borrowing and lending money; and

(d) doing all such other things or acts as may lawfully be done by a body corporate.

Functions of the Directorate.

6. The functions of the Directorate are to—

(a) formulate and enforce quality assurance standards in the in the manufacture, distribution and use of veterinary medicines to safeguard human and animal health and the environment;

(b) in consultation with the Director of Veterinary Services, regulate the use of veterinary medicine for the treatment of animals under the Animal Diseases Act; Cap 364

(c) consider applications for approval for market authorization of veterinary medicines;

(d) set quality assurance standards for training in the management of veterinary medicines as directed by the Kenya Veterinary Board;

(e) collaborate with the Kenya Veterinary Board in regulating training in the management of veterinary medicines;

(f) inspect and approve premises in which the manufacture, sale or supply of veterinary medicine is conducted;

(g) appoint and gazette veterinary medicine inspectors;

(h) establish the standard operating procedures for veterinary medicine inspectors;

(i) regulate veterinary pharmacy practices;

(j) categorize veterinary medicines and the qualification of persons authorized to trade in each category and review the categories every five years;

(k) regulate clinical and non-clinical trials of veterinary medicines by individuals and institutions to be involved in the trials;

(l) regulate the manufacture, importation, exportation, handling, advertisement, labeling, sale and disposal of veterinary medicines;

(m) register all veterinary medicines manufactured or imported for use in the country or exported from the country;

(n) monitor the market for and take measures necessary for the elimination of trade in illegal and counterfeit veterinary medicines;

(o) establish systems of pharmaco-vigilance and conduct pharmaco-vigilance of veterinary medicines through regular inspections and surveys;

(p) enforce good manufacturing practice for veterinary medicines as approved by the Council;

(q) develop, apply and from time to time review guidelines to be used in the inspection and ensuring compliance with good manufacturing practice;

(r) ensure that the promotion and marketing of veterinary medicine is in accordance with the approved product information;

(s) publish, on an annual basis, a notice in the Kenya Gazette inviting the public to note and inspect the register of veterinary medicines and the list of approved veterinary pharmacy practices within such period and at such place as may be specified in the notice;

(t) consider, grant, issue or revoke authorizations and certificates in accordance with these Regulations;

(u) collaborate with other regulatory agencies including the Public Health (Standards) Board in section 27 of the Food, Drugs and Chemical Substances Act,, the Pest Control Products Board established under section 5 ofthe Pest Control Products Act and the Central Board of Health established under section 3 of the Public Health Act to carry out its mandate; and

Cap 254.
Cap 346.
Cap 242

(v) undertake any other thing necessary for the effective carrying out of its mandate under this or any other Act.

Powers of the Council.

7. The Council shall have all the power necessary or expedient for the effective discharge of its functions under these Regulations and any other law, and in particular the power to—

(a) control, supervise and manage the assets and liabilities of the Directorate;

(b) determine the provision to be made for capital and recurrent expenditure and for the reserves of the Directorate;

(c) seek and receive any grants or donations and make legitimate disbursements from such grants and donations for its purposes;

(d) levy fees and charges for its services as provided in these Regulations;

(e) enter into association with other bodies within or outside Kenya which the Council may consider desirable or appropriate;

(f) invest funds of the Directorate not immediately required in securities in which trustees are empowered to invest under the Trustee Act, and in other securities which may be approved for the purpose, by the Cabinet Secretary for the time being responsible for Finance;

Cap. 167.

(g) establish and support investment and trust funds for the benefit of employees or ex-employees of the Directorate or dependants of such persons, to grant pension, benefits and allowances and to make such payments towards insurance as required under the relevant laws;

(h) open and operate such accounts as are necessary for the funds of the Directorate, with a bank or financial institution

licensed to conduct banking business under the Banking Act; Cap.488.

(i) recruit, support, discipline or dismiss the staff and inspectors of the Directorate;

(j) in consultation with Salaries Remuneration Commission, determine the terms and conditions of employment of the staff and inspectors of the Directorate;

(k) establish branch offices of the Directorate, to the extent that is practicable, to ensure accessibility of its services by all Kenyans;

(l) superintend, regulate and assist branch offices, auxiliaries, committees and other forms of organizations established to advance the interest of the Directorate;

(m) perform all things necessary or incidental to attain the objectives of the these Regulations or any other written law.

Composition and appointment of the Council.

8. (1) The Council shall be appointed by the Cabinet Secretary and shall consist of—

(a) the Director of Veterinary Services who shall be the Chairperson;

(b) the Registrar of the Pharmacy and Poisons Board; Cap 244

(c) the Chief Executive Officer of the Kenya Veterinary Board;

(d) the Principal Secretary for the time being responsible for Finance;

(e) the Principal Secretary for the time being responsible for animal health matters;

(f) three veterinary surgeons nominated by the Kenya Veterinary Board;

(g) one veterinary technologist from the veterinary pharmaceutical industry nominated by the Kenya Veterinary Board; and

(h) the Chief Executive Officer of the Directorate who shall be the Secretary to the Council and shall be an *ex-officio* member.

(2) A person appointed under paragraph (1)(f) shall be nominated by the Kenya Veterinary Board from a list of five names drawn from the veterinary pharmaceutical industry including a trainer in veterinary pharmacology submitted by a registered professional association representing the interests of veterinary surgeons countrywide.

(3) A person appointed under paragraph (1)(g) shall be nominated by the Kenya Veterinary Board from a list of three names from the veterinary pharmaceutical industry submitted by the registered association representing the interests of veterinary paraprofessionals.

(4) The nominating bodies referred to under paragraphs (2) and (3) shall observe Constitutional principles relating to gender, youth, persons with disability and minorities in identifying the persons whose names shall be submitted for nomination by the Kenya Veterinary Board for appointment to the Council.

(5) The Cabinet Secretary shall appoint the members of the Council by notice in the Kenya Gazette.

(6) The Council shall conduct its affairs in the manner set out in the First Schedule.

(7) 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.

(8) The members appointed under paragraph (1) (b), (d) and (e) may, in writing, designate representatives to attend the meetings of the Council on their behalf.

(9) The members of the Council in paragraphs (f), (g) and (h) may—

(a) at any time resign from office by notice in writing to the Cabinet Secretary;

(b) be removed from office by the Cabinet Secretary, on the advice of the Council if the member –

(i) is declared bankrupt;

(ii) is absent from three consecutive meetings of the Council, without the permission of the Chairperson;

(iii) is convicted of a criminal offence and, sentenced to a term of imprisonment of more than six months;

(iv) is unable or unfit, due to physical or mental illness, to perform the functions of his office; or

(v) has failed to comply with the provisions of Chapter Six of the Constitution

(10) The Cabinet Secretary shall, on the recommendation of the Council, appoint a relevant person 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 (9) (b) and the person appointed under this sub-Regulation shall serve until the end of the term of the Council.

(11) Where a vacancy arises under paragraph (10), the Cabinet Secretary shall undertake a fresh recruitment process to fill the vacancy.

Co-option of specialized persons.

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.

Meetings of the Council.

10. The conduct and regulation of the business and affairs of the Council shall be as provided in the First Schedule but subject thereto, the Council shall regulate its own procedure.

Conflict of interest.

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.

(2) The disclosure of interest shall be recorded in the minutes of the meeting at which it is made.

(3) A member or employee of the Council shall not carry out an business or trade with the Council.

(4) A member or staff of the Council 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.

Common seal and logo.

12. (1) The Directorate shall have a common seal which shall be kept by the Chief Executive Officer.

(2) The affixing of the seal shall be authenticated by signature of the chairperson and the Chief Executive Officer and in his absence, the signature of any other member authorized by resolution of the Council.

Chief Executive Officer.

13. (1) There shall be a Chief Executive Officer who shall be 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.

(2) A person shall be qualified for appointment as a Chief Executive officer, if that person—

(a) is a Kenyan citizen;

(b) holds a degree in veterinary medicine from a university recognized by the Kenya Veterinary Board;

(c) has at least ten years professional experience in veterinary medicine regulation, of which at least five years are at senior management level; and

(d) satisfies the requirements of Chapter Six of the Constitution.

(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.

(4) The Chief Executive Officer shall hold office for a term of five years and shall be eligible for reappointment for one further term.

(5) The Chief Executive Officers shall, in the performance of the functions and duties of office, be responsible to the Council.

(6) Without prejudice to the provisions of paragraph (5), the Chief Executive Officer shall—

(a) be responsible for—

(i) carrying into effect the decisions of the Council;

(ii) day-to-day administration and management of the affairs of the Directorate;

(iii) supervision of the staff of the Directorate;

(b) be the Registrar of veterinary medicines; and

(c) perform such other duties as may be assigned by the Council.

Removal of the Chief Executive Officer.

14. (1) The Chief Executive Officer may be removed from office by the Council in accordance with the terms and condition of service, for—

(a) inability to perform functions of the office arising out of physical or mental infirmity;

(b) gross misconduct or misbehavior;

(c) incompetence or negligence of duty;

(d) violation of the Constitution and any other written law; or

(e) any other grounds specified in the terms and conditions of service.

(2) Where the question of the removal of the Chief Executive Officer under paragraph (1) arises, the Council shall—

(a) inform the Chief Executive Officer in writing of the reasons for the intended removal; and

(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.

Veterinary medicines inspectors.

15. (1) The Council shall employ such veterinary medicines inspectors as it deems necessary.

(2) A person shall be qualified for appointment as a veterinary medicines inspector if that person —

(a) is a veterinary surgeon or technologist; or

(b) holds at least a diploma in animal health or other qualification recognized by the Council; and

(c) has at least five years post qualification experience in a relevant field.

Staff.

16. The Council may employ such staff as it deems appropriate for the effective performance of its functions.

Code of conduct.

17. The members and the employees of the Council shall subscribe to the leadership and integrity code set out in the Fourth Schedule.

Protection from personal liability.

18. Nothing done by a member of the Council or by any person working under the instructions of the Council shall, if done in good faith for the purpose of executing the powers, functions or duties of the

Council under these Regulations render such member or officer personally liable for any action, claim or demand.

PART III— MANUFACTURING, IMPORTATION AND REGISTRATION OF VETERINARY MEDICINES

Veterinary medicines to be registered.

19. (1) 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.

(2) Every person transporting a veterinary medicine in transit shall declare the veterinary medicine at the port of entry and exit.

Manufacturing permit.

20. A person who intends to manufacture veterinary medicine shall make an application to the Council for a manufacturing permit.

Manufacturing of veterinary medicines.

21. (1) The Council shall, on receipt of an application made under regulation 20, 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 practice.

(2) The inspector instructed under paragraph (1) shall submit the results of the inspection to the Council and the applicant in writing.

(3) A manufacturer shall ensure that every stage in the manufacture of a veterinary medicine is carried out based on good manufacturing practices.

(4) A manufacturer shall not manufacture a veterinary medicine unless the manufacturing plant has been inspected and licensed in accordance with this Regulation.

(5) A person shall not use any premises, for the purposes of manufacturing, formulating, packaging, selling or storing veterinary medicine unless that person is in possession of a licence issued under these Regulations in respect of that premises.

(6) Where an inspector has approved the compliance by the manufacturer, the Council shall on payment of the prescribed fee, issue a licence as set out in Form I.3 set out in the a Third Schedule.

(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.

Powers of inspectors with regard manufacturing plants.

22. (1) An inspector appointed under these Regulations shall have power with regard to manufacturing plants to—

(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 Council; or

(b) order the immediate closure of a manufacturing plant where its continued operation appears to pose a serious threat to life and safety.

(2) An inspector who has ordered the closure of a plant under paragraph (1)(b) shall within twenty-four hours of the closure notify the Council of the closure and shall provide reasons for the closure.

(3) On receipt of the notification under paragraph (2), the Council shall direct the owner of the plant to take such measures as the Council may direct to ensure conformity with these Regulations.

(4) A manufacturer who fails, within fourteen days of receipt of the directive made by the Council under paragraph (3), to take the measures indicated in the directive shall have its licence revoked.

(5) The Council shall publish in at least one newspaper of wide national circulation the name of a manufacturing plant closed and whose licence has been revoked under this Regulation and shall place a notice of the closure at the entrance of such plant.

(6) The protection of right to property under Article 40 of the Constitution shall be limited for purposes of maintenance of veterinary medicine standards for the protection and safety of the public.

Application for registration of a veterinary medicine.

23. (1) An application for registration of—

(a) a veterinary medicine shall be in accordance with Form A set out in the Third Schedule; and

(b) a veterinary medicine used as pesticides shall be Form B set out in the Third Schedule.

(2) An applicant shall, in addition to the information required to be paragraph (1), furnish such further information and material as may be required by the Council for the proper evaluation of the veterinary medicine in respect of which the application is made.

(3) The Council shall, on approval of an application made under this Regulation and on payment of the prescribed fees, register the veterinary medicine or veterinary pesticide and issue a certificate in Form D1 or D2, respectively set out in the Third Schedule.

(4) A certificate of registration issued under these Regulations shall, unless suspended or revoked, be in force for a period of five years.

(5) The Council 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.

Renewal of registration of veterinary medicine.

24. (1) A person may make an application to the Council, for renewal of registration of a veterinary medicine in Form E set out in the Third Schedule.

(2) The Council shall, before renewing registration under this Regulation conduct a pharmaco-vigilance study on the manufacturer.

(3) An applicant shall on receipt of approval for renewal of registration from the Council, make payment of the fees as prescribed in the Fifth Schedule.

Clinical and non-clinical trials and toxicity testing.

25. (1) The Council may require that a clinical and non-clinical trial and toxicity testing be done before the registration of a veterinary medicine.

(2) Despite paragraph (1) a veterinary pesticide shall not be registered unless an efficacy and an acute toxicological study is carried out by an accredited laboratory.

(3) A person who or institution which intends to apply for accreditation under this Regulation shall, before making such application, obtain approval from the Council.

(4) A person who or institution which desires to conduct clinical and non-clinical trials and toxicity testing shall apply to the Council for accreditation.

(5) The cost of any clinical trial or toxicity testing shall be borne by the applicant.

Conditions for registration of veterinary medicines and pesticides.

26. (1) A veterinary medicine and pesticide shall not be registered unless a laboratory analysis has been carried out by an accredited laboratory.

(2) A person who intends to register a veterinary medicine shall submit to the Council a certificate of analysis from an accredited laboratory together with the application for registration of the veterinary medicine

Veterinary Medicines Registration Committee.

27. (1) There is hereby established a standing committee of the Council to be known as the Veterinary Medicines Registration Committee.

(2) The Committee shall be responsible for matters relating to registration of veterinary medicines under these Regulations and in particular shall be responsible for—

(a) evaluating applications for veterinary medicines registration and shall make recommendations to the Council; and

(b) issuing provisional approval pending the issuance of the veterinary medicines registration certificate by the Council.

(3) A provisional certificate issued under paragraph (2)(b) shall be valid for a period of not more than three months.

(4) The Council shall consider an application made under this Regulation, and if satisfied of the safety, efficacy and quality of the veterinary medicine or veterinary pesticide, shall register the veterinary medicine in accordance with Form C1 and C2 set out in the Third Schedule.

(5) Upon registration of a veterinary medicine under paragraph (4), the applicant shall be issued with a certificate of registration in Form D1 or D2 set out in the Third Schedule.

(6) The Council 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—

(a) the name under which the veterinary medicine may be sold;

(b) the labeling;

(c) the statement of the representations to be made for the promotion of the veterinary medicine in respect of the-

(i) claim to be made for the veterinary medicine;

(ii) route of administration;

(iii) dosage;

(iv) contra-indications, side effects and precautions, if any;

(v) package size;

(vi) withdrawal period for food producing animals;

(vii) proposed category; and

(viii) shelf life.

Rejection of application for registration of a veterinary medicine

28. The Council shall, if it is not satisfied as to the safety, efficacy or quality of the veterinary medicine, reject the application for the registration of the veterinary medicine and inform the applicant, in writing, the reasons for rejection.

Registration of veterinary medicine researched outside Kenya

29.(1) The Council may, before registering a new veterinary medicine for which the research work has been conducted in another country and its efficacy, safety, and quality established in that country, require an investigation on the pharmaceutical, 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.

(2) Despite paragraph (1), the Council may register a new veterinary medicine and require the investigations and clinical trials specified therein to be conducted after its registration.

Suspension and revocation of certificate of registration.

30. (1) The Council may suspend or revoke a certificate of registration issued under these Regulations for such period as the Council may determine.

(2) The Council shall not revoke or cancel the certificate of registration unless—

(a) where matters stated in the application on which the certificate of registration was granted were false or incomplete in any material particular;

(b) where provision of the certificate of registration has to a material extent been contravened by the holder of the certificate;

(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

(d) where new information has been discovered by the Council which renders the veterinary medicines unsafe or dangerous.

(3) Where a certificate has been revoked under paragraph (2) (d), the Council shall on delivery of the information to the manufacturer-

(a) inspect the plant to ensure all the medicine or the relevant batch has been destroyed;

(b) disseminate the information to the public through a newspaper advertisement in at least two daily newspapers of nationwide circulation; and

(c) recall any medicine which has been distributed.

Period for renewal of registration and retention of veterinary medicine.

31. (1) The Council may grant the renewal of registration as provided under regulation 24 for a period not exceeding five years.

(2) On the expiry of five years a veterinary medicine may be retained in the register upon an application made by the certificate holder which shall—

(a) include a declaration that the requirements met by the veterinary medicine during registration has not changed; and

(b) include payment of the requisite fees.

PART IV – CLASSIFICATION AND CATEGORIZATION OF VETERINARY MEDICINES

Classification of Veterinary Medicines.

32. (1) The Cabinet Secretary shall classify veterinary medicines in the classes set out in Part I of the Second Schedule.

(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.

Categorization of Veterinary Medicines.

33. (1) The Cabinet Secretary shall categorize veterinary medicines as set out in Part II of the Second Schedule.

(2) The Cabinet Secretary shall be guided by the Council on the categorization of veterinary medicines and shall place the veterinary medicines in the following categories—

(a) Category I relating to prescription only medicine–Veterinary Surgeon which shall comprise two sub-categories as follows—

(i) Category IA relating to Controlled Veterinary Medicines includes products which contain narcotic or psychotropic substances or other substances very dangerous at small quantities;

(ii) Category IB relating to other prescription only medicine, comprising 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 qualification;

(b) Category II relating to prescription only medicine veterinary surgeon, pharmacist, and veterinary technologist who has served for at least five years in a veterinary pharmacy which contains—

(i) veterinary medicines for use in food-producing animals;

(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—

(a) the administration of the veterinary medicine is restricted to formulations requiring no particular knowledge or skill in using the product;

(b) 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;

(c) the summary of product characteristics of the veterinary medicine does not contain any warnings of potential serious side effects deriving from its correct use;

(d) the veterinary medicine or any other product containing the same active substance has not previously been the subject of frequent serious adverse reaction;

(e) the summary of product characteristics does not refer to contra-indications related to other veterinary medicine commonly used without prescription;

(f) the veterinary medicine is not subject to special storage conditions;

(g) there is no risk for consumer safety as regards residues in food obtained from treated animals even where the veterinary medicines has been used incorrectly; and

(h) there is no risk to human or animal health as regards the development of resistance to antimicrobials or anti-helmintic substances even where the veterinary medicine containing those substances is used incorrectly; and

(j) veterinary medicines that may cause effects that impede or interfere with subsequent diagnostic or therapeutic measures.

(c) Category III relating to authorised veterinary medicine general sales list which may be traded by veterinary surgeons and all categories of veterinary paraprofessionals and includes—

(i) pest control veterinary medicines provided that the medicine are 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.

(d) Category IV which includes alternative veterinary medicine general sales list .

Use of veterinary pesticides.

34. (1) A veterinary pesticide shall be—

(a) sold only in the original sealed and labeled package as registered by the Council;

(b) stored in accordance with the instructions on the label on the original container; and

(c) used according to the instructions on the label.

(2) The empty container of a veterinary pesticide shall be disposed in accordance with the instructions given on the label.

(3) A person who removes or defaces a label on a veterinary pesticide or package commits an offence.

(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.

PART VI— VETERINARY PHARMACY

Standards of Veterinary Pharmacy.

35. (1) A veterinary pharmacy shall satisfy the following minimum standards—

(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-complementary businesses;

(d) have restricted access by personnel to Category I and II veterinary medicine; and

(e) be vermin-proofed, including protection against insects and rodents;

(2) A veterinary pharmacy shall—

(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 Council, for safe disposal of expired veterinary medicines;

(h) be operated by competent staff as provided for in the permit;

(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 five years; and

(p) provide separate sanitary facilities for each gender.

Qualifications to operate a veterinary pharmacy

36. A person who is a veterinary surgeon, or holds an equivalent qualification in matters of pertaining to veterinary medicines as determined by the Council, may apply to the Council for a permit to undertake a veterinary pharmacy.

Council to approve veterinary pharmacy businesses

37. (1) The Council shall have power to approve any of the following types of veterinary pharmacy businesses—

(a) manufacturing of veterinary medicines;

(b) wholesaling of veterinary medicines; and

(c) retailing of veterinary medicines.

(2) Upon approval of the veterinary business specified under paragraph (1), the Council shall register the veterinary pharmacy premises in Form J set out in the Third Schedule.

Practicing permit

38. (1) A person shall not practice the business of veterinary pharmacy unless he holds a valid practicing permit issued by the Council.

(2) A person who intends to practice the business of veterinary pharmacy shall make an application in Forms H1, H2 and H2, respectively of the Third Schedule.

(3) The Council shall issue a practicing permit if the premises in which the applicant intends to operate has been approved by the Council in accordance with these Regulations.

(4) An application for a practicing permit shall be in —

(a) Form I.1 for veterinary pharmacy practitioner;

(b) Form I.2 for a wholesaler dealer permit; or

(c) Form I.3 for manufacturers' permit.

(5) An applicant under paragraph (1) shall, on approval of the application, by the Council, pay the fee prescribed in the Fifth Schedule.

(6) The Council, upon confirming that the applicant has satisfied the conditions of a permit, and upon payment of the fee under paragraph (4) issue an applicant with a practicing permit as set out in Form A set out in the Third Schedule for veterinary pharmacy practices and Form B for wholesale pharmacy practice.

(7) The practice permit 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.

(8) The Council shall by the 31st March of every year publish, in the Kenya Gazette or in a newspaper of wide national circulation, the registered veterinary pharmacy businesses.

(9) A person who conducts the business of veterinary pharmacy in premises not registered by the Council 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.

Practice permit to be displayed

39. (1) A person who carries on the business of a veterinary pharmacy shall display his practice permit on a conspicuous place within the premises in which the business is being carried on.

(2) A person who contravenes the provisions 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.

Wholesale permit.

40. A person who intends to trade in veterinary medicines, in bulk , shall make an application to the Council for a wholesale permit and support the application with the following—

(a) a certified copy of the certificate of registration or incorporation of the business name or body corporate and the memorandum and articles of association;

(b) provide evidence that the business is under the management of a supervisor who—

(i) is a registered veterinary surgeon permitted to carry out the business of veterinary pharmacy; and

(ii) is a member of the Board of directors of the body corporate, and who is not acting in a similar capacity for any other body corporate.

Retail permit.

41. (1) A person who intends to trade in veterinary medicines as a retailer shall make an application to the Council for a retail permit in Form H set out in the ThirdSchedule

(2) This regulation shall be applicable to a manufacturer and a wholesaler of veterinary medicines who desires to carry out retail trade.

PART VII—VETERINARY PHARMACY AND COMPLEMENTARY BUSINESSES

Complementary businesses.

42. (1) A veterinary pharmacy may be conducted alongside complementary businesses including the sale of human medicines, horticultural chemicals, agro-forestry chemicals and fertilizer, animal foodstuffs, seeds and agricultural equipment.

(2) The building or premises of a veterinary pharmacy stocking or trading in complementary 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 products from any other products.

(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 medicines and veterinary pesticides such that no mixing of the two classes of products is permissible.

Stock, supply and distribution of veterinary medicine.

43.(1) A veterinary medicine shall be supplied or distributed only through a wholesale or retail business registered as a veterinary pharmacy business.

(2) A holder of wholesale or veterinary pharmacy permit issued by the Council may sell veterinary medicines in bulk to registered retail dealers.

(3) A holder of a retail dealer permit, issued by the Council, may sell veterinary medicines to the public.

(4) A person shall not supply authorised human medicinal product for administration to an animal other than a product supplied by a veterinary surgeon or in accordance with a written prescription from a veterinary surgeon.

(5) A veterinary pharmacy practitioner 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.

PART VIII— MARKET AUTHORIZATION

Authorization to import or export veterinary medicine.

44. (1) A person who intends to import or export a veterinary medicine shall apply to the Council for a permit in Form K set out in the Third Schedule.

(2) The Council shall in determining the application under paragraph (1) 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 permit in Form L set out in the Third Schedule .

(3) A holder of a market authorization may apply to the Council for a wholesale permit to authorize him to import the veterinary medicine specified in the authorization.

(4) An authorised wholesale dealer may import a veterinary medicine if—

(a) the authorization covers the veterinary product; and

(b) the wholesale dealer has acquired the written consent of the holder of the market authorisation in writing before importation.

(5) A veterinary surgeon may, with approval of the Council, import an orphan veterinary medicine.

PART V – VETERINARY MEDICINE INSPECTORS

Appointment of veterinary medicine inspectors.

45. The Council shall appoint duly qualified persons on such terms and conditions of service as it may deem appropriate, to serve as veterinary medicine inspectors.

Identification of veterinary medicines inspector.

46.(1) The Council shall publish in the Kenya Gazette every inspector appointed under regulation 45 and issue each inspector with an official identity card which shall have a passport size photo of the inspector , duly stamped and signed by the Chief Executive Officer or his authorized agent.

(2) Every inspector shall, in conducting inspections under these Regulations, identify himself using the identity card issued under paragraph (1).

(3) A person who ceases to be an inspector shall surrender his identify card to the Chief Executive Officer or his authorized agent.

Powers of veterinary medicines inspectors.

47. (1) An inspector shall have the power, at all reasonable times, to—

(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, or any article stored or offered for sale or used in the business; or

(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.

(2) An inspector shall-

(a) for the purpose of inspecting a veterinary medicine use Form F set out in the Third Schedule; and

(b) for any impounding of suspect veterinary medicines, use Form G set out in the Third Schedule.

(3) An inspector shall observe confidentiality in the findings of his inspection.

(4) An inspector shall be liable for any act of negligence he may commit in the performance of his duties.

PART X—FINANCIAL PROVISIONS

Funds of the Directorate.

48. (1) The funds of the Directorate shall comprise of –

(a) such monies as may be appropriated by Parliament for the purposes of the Directorate;

(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

(c) monies from any other source provided for , donated or lent to the Directorate.

Financial year.

49. The financial year of the Directorate shall be the period of twelve months from first July to thirtieth of June.

Annual estimates.

50. (1) Three months before the commencement of each financial year, the Council shall cause to be prepared estimates of revenue and expenditure of the Directorate for that year.

(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—

(a) the payment of salaries, allowances and other charges in respect of the staff of the Directorate;

(b) the payment of pensions, gratuities and other charges in respect of retirement benefits which are payable out of the funds of the Directorate;

(c) the proper maintenance of buildings and grounds of the Directorate;

(d) the acquisition, maintenance, repair and replacement of the equipment and other movable property of the Directorate; and

(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.

(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.

(4) The Directorate shall not increase any sum provided in the estimates without the consent of the Cabinet Secretary.

Investment of funds.

51. The Council may invest any of the funds of the Directorate in a manner approved by the Treasury for the investment of trust funds.

Accounts and Audit.

52. (1) The Council shall cause to be kept all proper books and records of accounts of the income, expenditure, assets and liabilities of the Directorate.

(2) The accounts of the Directorate shall be audited in accordance with the Public Finance Management Act, 2012. No. 18 of 2012.

PART IX— OFFENCES

Offences.

53. A person commits an offence if that person—

(a) imports, exports, manufactures, stores, distributes, sells or otherwise handles a veterinary medicine that has not been registered under these Regulations;

(b) imports a veterinary medicine without a permit issued under these Regulations;

(c) manufactures, stores, distributes or sells a veterinary medicine in premises which have not been registered under these Regulations;

(d) presents for sale or distribution, expired, adulterated, Counterfeit or unlabeled veterinary medicines;

(e) sells a veterinary medicine in any form other than the original sealed and labeled package, as registered with the Directorate;

(f) sells or distributes a veterinary medicine in any other area other than a registered premises;

(h) uses a veterinary medicine for purposes other than that for which it was registered, prescribed or dispensed;

(i) supplies human medicinal product for administration to an animal in contravention of these Regulations;

(j) is in possession of a Category I or Category II veterinary medicine other than in accordance with these Regulations;

(k) advertises a veterinary medicine in contravention of these Regulations;

(l) buys a veterinary medicine for resale in bulk while not being in possession of a wholesale dealer permit issued under these Regulations;

(m) sells a veterinary medicine to the public while not being in possession of a retail dealer's permit issued in accordance with these Regulations;

(n) undertakes research on imported and unregistered veterinary medicine without authorization from the Council;

(o) obstructs or fails to assist the Council or veterinary medicine inspector in the performance of their lawful duties under these Regulations;

(p) provides the Council or inspector with false or misleading information;

(q) operates a veterinary pharmacy after it has been closed by an inspector; or

(r) contravenes any provision of these Regulations.

Officers of corporations.

54. 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.

Passing confidential information without authorization.

55. A member of the Council or staff of the Directorate, who—

(a) being in possession of confidential information, however obtained without authorization of the Council—

(i) divulges it; or

(ii) attempts, offers or threatens to divulge it

other than in accordance with these Regulations or other written law; or

(b) willfully obtains or seeks to obtain confidential information to which he is not entitled, commits an offence.

Penalties.

56. 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.

PART X— GENERAL PROVISIONS

Advertising standards for veterinary medicines.

57. (1) A person who intends to advertise a veterinary medicine, shall make an application to the Council for authority to advertise.

(2) The Council may, on payment of the requisite fee and subject to such conditions as the Council or these Regulations may impose, grant the authorization applied for under paragraph (1).

(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 Council.

(4) A veterinary medicine listed under Category I and II shall not be advertised unless—

(a) in the case of a veterinary medicine listed under Category I, the advertisement is aimed at veterinary surgeons; and

(b) in the case of a veterinary medicine listed under Category II, the advertisement is aimed at veterinary surgeons or suitably qualified persons as recognized by the Council.

(5) A veterinary medicine listed in Category III and IV may be advertised to general members of the public.

Exemptions to Regulations.

58. (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 supplements with no therapeutic claim.

Discretion of Council.

59. The Council shall have the discretion to—

(a) approve the importation and use of any veterinary medicine for handling emergency situations;

(b) cancel the registration of any veterinary medicine that is considered to be harmful to animal and human health and the environment; or

(c) restrict the use of any specified veterinary medicine.

Copy of certificate or authorization.

60. (1) A person who has been issued with a certificate or authorization under these Regulations may, if the certificate or authorization is defaced, damaged or lost, on application to the Council and on payment of the prescribed fee, be issued with a copy of the certificate.

(2) The copy of a certificate or authorization issued under paragraph (1) shall-

(i) be issued only where the document is in force at the time the application is made;

(ii) be valid for the same period as the original document; and

(iii) bear the words "DUPLICATE COPY".

Fees.

61. Any fees payable under this Act is as set in the Fifth Schedule.

Supercession.

62. These Regulations shall supersede any other Regulations on matters concerning veterinary medicines.

Transition and validity of licences and permits.

63. Upon the commencement of these Regulations any certificate in force shall be deemed to have been issued under these Regulations and shall remain in force until its expiry.

FIRST SCHEDULE (r.8 (6))

CONDUCT OF THE AFFAIRS OF THE COUNCIL

Meetings of the Council.

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.

2. (1) The Council shall at its first meeting elect its vice-chairperson from among the three members appointed under regulation 8(3)(f).

(2) 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.

Quorum

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

Decisions of Council

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.

Minutes

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.

(2) The deliberations and minutes of meetings of the Council shall be confidential.

Vacancy not to invalidate proceedings

6. No proceedings of the Council shall be invalid by reason only of a vacancy among the members thereof.

Council to determine own procedure

7. Subject to this Schedule, the Council may determine its own procedure.

Invitation of other persons.

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.

SECOND SCHEDULE (32(1)& 33(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 nutrients

(i) Vitamins.

(ii) Minerals.

(iii) Amino acids.

(iv) Oils.

(v) Sugars.

4. Equipment and materials.

(i) Surgicals.

(ii) Veterinary medicine administration devices.

(iii) Any other material and equipment of veterinary relevance

5. List of alternative medicines.

(i) Preventive

(ii) Curative

(iii) Performance enhancers

6. List of poisons.

(i) Acaricides

(ii) Molluscicides

(iii) Insecticides

(iv) Rodenticides

(v) Any other pesticides of veterinary relevance

(vi) And other ecto-parasiticides

(vii) 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. Etoxeridine;
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 derivates, 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) Monofluroacetic 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-amino-benzenesulphonamide 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) Pephanazine

(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) Tripelennamine

(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) Halogeneted 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) Monofluroacetic

(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 quadroxalatc

(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) Mephenesin; its esters.

(15) Monofluroacetic 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) Rubefacent 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.23(1)& 38(6))

APPLICATION FOR REGISTRATION OF A VETERINARY MEDICINE

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

The Registrar

Veterinary Medicines Directorate

KABETE

Application Number		
Date of submission of the dossier		
Name of the 1st Evaluator		Signature
Name of the 2nd Evaluator		Signature
Date of 1st evaluation		
Date of 2nd Evaluation		
Number of files received		
CONCLUSION OF THE ASSESSMENT RECOMMENDED *(no outstanding issues)* QUERY RAISED *(Indicate the sections where query is raised)* REJECTED *(indicate the module(s) that led to the rejection)* *(Please delete which does not apply)*		
TYPE OF APPLICATION – VETERINARY PHARMACEUTICALS, BIOLOGICALS, NUTRIENTS, EQUIPMENT AND MATERIALS, ALTERNATIVE MEDICINE, POISONS (tick the applicable class)		
PART1: ADMINISTRATIVE INFORMATION		
SECTION 1: PARTICULARS OF THE VETERINARY MEDICINE		
1.1 Name and address of Applicant		
(Company) Name: Address: Country: Country Code: Office telephonenumber: Mobile telephone number: E-Mail:		
For VMD use only		

1.2	Trade Name of the veterinary medicine (Proprietary Veterinary Medicine Name)
For VMD use only	
1.3	International Non-proprietary Name (INN) of the Active Ingredient (AI)
For VMD use only	
1.4	Strength of Active Ingredient (AI) per unit dosage of the veterinary medicine:
For VMD use only	
1.5	Pharmaceutical Dosage form and route of administration of the veterinary medicine
1.5.1	Pharmaceutical Dosage form of the veterinary medicine:
1.5.2	Route*(s)* of administration (use current list of standard terms – British Pharmacopoeia)
For VMD use only	
1.6	Packing/pack size of the veterinary medicine:
For VMD use only	
1.7	Visual description of the veterinary medicine*(Add as many rows as necessary)*
For VMD use only	
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:
For VMD use only	
1.9	Pharmacotherapeutic group and Anatomical Therapeutic Chemical (ATC) Code
1.9.1	Pharmacotherapeutic group:
1.9.2	ATC Code: *(Please use current ATC code)*
1.9.3	If no ATC code has been assigned, please indicate if an application for ATC code has been made: ☐
For VMD use only	

1.10	Legal category
1.10.1	Proposed dispensing category:
1.10.2	For veterinary medicine subject to veterinary prescription: Controlled Veterinary Medicine (POM-V Category IA) or Other Prescription Only Medicine, (Category IB-POM-V) *(Please delete which does not apply)*
1.10.3	For veterinary medicine not subject to veterinary prescription:
For VMD use only	
1.11	Country of origin or country of release:
For VMD use only	
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

☐ Authorised Country: Date of authorisation (dd-mm-yyyy): Proprietary name: Authorisation Certificate number: ☐ Refused Country: Date of refusal (dd-mm-yyyy): Reason for Refusal:	☐ Withdrawn (by applicant after authorisation) Country: Date of withdrawal (dd-mm-yyyy): Proprietary name: Reason for withdrawal: ☐ Suspended/revoked (by competent authority) Country: date of suspension/revocation (dd-mm-yyyy): Reason for suspension/revocation: Proprietary name:
For VMD use only	

1.13	Pre-registration analysis of the Veterinary Medicine (Attach certificate of analysis from a laboratory recognized by the Directorate)
For VMD use only	

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 the veterinary medicine if different from the manufacturer.*(Add as many rows as necessary)*
Name: Company name: Address: Country: Country code: 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: Country code Office Telephone number: Mobile number: E-Mail:	
For VMD use only	
1.15	Good Manufacturing Practice (GMP) status of the manufacturer (s) of the veterinary medicine
For VMD use only	
1.16	Name and complete address of the Market Authorization holder of Manufacturer
Name: Company name: Address: Country: Country Code Office telephone number:	

Mobile number: E-Mail: If the Market Authorization holder is different to 1.1 above, explain and provide evidence for the relationship:								
For VMD use only								
1.17	Summary Veterinary Medicine Characteristics							
For VMD use only								
1.18 Batch number(s) of the veterinary medicine used in *(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/production finished veterinary medicine batches (kg)								
Ingredients	Administration Unit		Bioequivalence □batch number□		Primary stability □batch number□		Production □batch number□	
	Mg	%*	Kg	%*	Kg	%*	kg	%*
Core tablet / bolus / 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								
Please add / delete as many rows as necessary								
Subtotal 1								

Purified water/other solvent(s)								
Capsule shell / printing ink(*Please delete / change which does not apply*)								
Please add / delete as many rows as necessary								
Subtotal 2								
Grand total								
Equivalence of the composition or justified differences	The compositions of the bioequivalence, stability and validation batches are the same and differences are justified. (*Please delete / change which does not apply*)							
* Each ingredient is expressed as a percentage of the grand total. ** All components (……..) of the proprietary mixture are described in the compendia								
For VMD use only OVERALL QUERIES AND RECOMMENDATIONS FOR THIS PART								
PART2: CHEMICAL, PHARMACEUTICAL, NON-CLINICAL AND CLINICAL OVERVIEWS AND SUMMARIES								
2.1	*OVERALL TABLE OF CONTENTS OF PARTS 2, 3, 4, AND 5*							
2.2	*INTRODUCTION*							
2.3	*OVERALL QUALITY SUMMARY*							
For VMD use only								
2.3.1	OVERVIEW OF ACTIVE INGREDIENT(S) [AI(S)]							
2.3.1.1	General Information of the AI(S)							
2.2.1.1.1	Nomenclature							
For VMD use only								
2.2.1.1.2	Structure							
For VMD use only								
2.2.1.1.3	General Properties of the AI(s)							
For VMD use only								
2.3.1.2	Manufacture of the AI(S)							
2.3.1.2.1	Name and address of AI(s) Manufacturer							
For VMD use only								
2.3.1.2.2	Description of Manufacturing Process and Process Controls							

2.3.1.2.3	Control of Materials used in Manufacture of AI
2.3.1.2.4	Controls of Critical Steps and Intermediates
2.2.1.2.5	Process Validation and/or Evaluation
For VMD use only	
2.3.1.3	Characterization of the AI(S)
2.3.1.4	Control of the AI(S))
2.3.1.5	Reference Standards or Materials of the AI(S)
2.3.1.6	Container Closure System of the AI(S)
2.3.1.7	Stability of the AI(S)
For VMD use only	
2.3.2	APPENDICES
2.3.2.1	Facilities and Equipment
2.3.2.2	Adventitious Agents Safety Evaluation
2.3.2.3	Novel Excipients
For VMD use only	
2.4	SUMMARY OF NON-CLINICAL DOCUMENTATION AND CLINICAL DOCUMENTATION
2.4.1	FOR NEW CHEMICAL ENTITIES
2.4.1.1	Non-clinical overview
2.4.1.2	Non-clinical written and tabulated summaries
2.4.1.3	Clinical overview
2.4.1.3	Clinical summary
For VMD use only	
2.4.2	GENERIC VETERINARY MEDICINE APPLICATIONS
2.4.2.1	Clinical Overview and Summary
2.4.2.1.1	Veterinary Medicine Development Rationale
2.4.2.1.2	Overview of Biopharmaceutics Studies
2.4.2.1.3	Summary of Biopharmaceutics Studies and Associated Analytical Methods
2.4.2.1.4	Overview and Summary of *In Vitro* Dissolution Tests complementary to Bioequivalence Studies
2.4.2.1.5	Overview and Summary of *In Vitro* Dissolution Tests in support of a Biowaiver
For VMD use only	

For VMD use only OVERALL QUERIES AND RECOMMENDATIONS FOR THIS PART	
PART3: CHEMICAL-PHARMACEUTICAL DOCUMENTATION	
3.1	*TABLE OF CONTENTS OF PART3*
3.2	*BODY OF DATA*
3.2.1	PARTICULARS OF ACTIVE INGREDIENT(s) [AI(s)]
3.2.1.1	General Information of the AI(S)
3.2.1.2	Manufacture of the AI(S)
3.2.1.3	Characterization of the AI(S)
3.2.1.4	Control of the AI(S))
3.2.1.5	Reference Standards or Materials of the AI(S)
3.2.1.6	Container Closure System of the AI(S)
3.2.1.7	Stability of the AI(S)
3.2.2	PARTICULARS OF FINISHED VETERINARY MEDICINE
3.2.2.1	Description and Composition of the Veterinary Medicine (s)
3.2.2.2	Pharmaceutical Development of the Veterinary Medicine (s)
3.2.2.3	Manufacture of the Veterinary Medicine (s)
3.2.2.4	Control of Excipients for the Veterinary Medicine (s)
3.2.2.5	Control of the Veterinary Medicine (s)
3.2.2.6	Reference Standards or Materials of the Veterinary Medicine (s)
3.2.2.7	Container Closure System of the Veterinary Medicine (s)
3.2.2.8	Stability of the Veterinary Medicine (s)
3.2.3	APPENDICES
3.2.3.1	Facilities and Equipment
3.2.3.2	Adventitious Agents Safety Evaluation
3.2.3.3	Novel Excipients

PART4: NON-CLINICAL STUDY REPORTS FOR NEW CHEMICAL ENTITIES ONLY	
4.1	*TABLE OF CONTENTS OF PART4*
4.2	*STUDY REPORTS*
4.3	*LITERATURE REFERENCES*
PART5: CLINICAL STUDY REPORTS	
5.1	*NEW CHEMICAL ENTITIES ONLY*
5.1.1	Table of Contents of Part5
5.1.2	Tabular Listing of All Clinical Studies
5.1.3	Clinical Study Reports
5.1.4	Literature References
5.2	*INTERCHANGEABILITY OF GENERIC VETERINARY MEDICINE – (GENERIC VETERINARY MEDICINE APPLICATIONS ONLY)*
5.2.1	REPORTS OF BIOPHARMACEUTIC STUDY(IES)
5.2.1.1	Bioavailability (BA) study report
5.2.1.2	*In Vitro* Dissolution Tests
5.2.2.1.1	In vitro dissolution tests complementary to bioequivalence studies
5.2.2.1.2	In vitro dissolution tests in support of biowaiver
5.2.3	Other Clinical study data done to support efficacy and safety of the product
5.3	*SAFETY AND RESIDUES DOCUMENTATION (FOR VETERINARY MEDICINES USED IN FOOD ANIMALS)*
5.3.1	Requirements for Animal Safety
5.3.1.1	Laboratory Animal Studies
5.3.1.2	Target Animal Safety Studies
5.3.2	Requirements for Human Safety
5.3.2.1	Laboratory Animal Toxicity Studies
5.3.2.2	Microbiological Safety Studies (for antimicrobial products)
DECLARATION BY AN 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 requirements for advertisements of veterinary 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 B (r.23 (b))

APPLICATION FOR THE REGISTRATION OF VETERINARY PESTICIDES

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

The Director

Veterinary Medicines Directorate

KABETE

Information for Applicants

1. The application form must be completed by a duly authorized person.

2. Every application must be accompanied by 3 copies of the draft label as per VMD requirements.

3. The applicant may be required to submit:-

(a) a sample of the veterinary pesticide;

(b) a sample of the technical grade of its active ingredient;

(c) a sample of the laboratory standard of its active ingredient;

(d) any other sample as may be required by the Council.

4. The application must be accompanied by a technical dossier as per VMD data Requirements.

5. An applicant who is not a resident in Kenya shall appoint as an agent a person who is permanently resident in Kenya and duly recognized by the Veterinary Medicines Directorate.

PURPOSE OF APPLICATION (tick as appropriate)

a. Veterinary pesticide containing a new active ingredient	☐
b. Veterinary pesticide where source of active and/or formulation is not identical to that of a registered product	☐
c. Registration transfer	☐
d. Amendments to existing registration	☐

e. Other (Explain)..... .....
Will the product be marketed under own label? Yes ☐ No ☐ If no specify.....
Proposed date of marketing.....

1. APPLICANT	
1.1 Identification	
Name of applicant / Corporate name of company	
Business Reg No.:	
Name of registration holder	
Name of local agent in country: (if different from registration holder)	
1.2 Status: (Importer/formulator/distributor)	
Country of origin and country code	
1.3 Physical Address	
1.4 Postal Address:	
1.5 Office Telephone(and code):	
1.6 Mobile:	
1.7 e-Mail:	
1.8 Status: 1.9 (Importer/formulator/distributor)	

Business Registration No. of Importer/formulator/distributor(if different from applicant) :	
1.2 Identification	
Name of applicant / Corporate name of company	
Business Reg No.:	
Name of registration holder	
Name of local agent in country: (if different from registration holder)	
1,2.1 Status: (Importer/formulator/distributor)	
1.2.2 Name:	
1.2.2 Country of origin and area code	
1.2.3 Physical Address	
1.2.4 Postal Address:	
1.2.5 Office Telephone (and code):	
1.2.6 Mobile (and code):	
1.3 e-Mail:	
Veterinary Pesticide details	
2.1 Designation (Description of product)	Trade name:
	Trade mark:
	Trade mark holder:
2.2. Function of veterinary pesticide: (eg. Insecticide, acaricides etc.)	
2.3 Intended use:,	
2.4 Target pest(s), vector(s) and host(s)	
2.5 Method, dosage rates and frequency of application:	
2.6 Type of formulation: (eg. Emulsifiable Concentrate, Wetable powder, etc.)	

2.7(a) Is the veterinary pesticide registered in country of manufacture? b) Is the veterinary pesticide registered in the country of formulation?	Yes ☐ No ☐ If no, give reasons Yes ☐ No If no, give reasons
2.8 Registration in SEARCH* country/ies: (names)	
2.9 Existing registration No(s) and country(s).	
2.10 Customs Tariff Code:	

3. COMPOSITION OF ACTIVE INGREDIENT(S) (Technical grade) (Information on active ingredient(s) (A.I) may be attached in sealed envelope)

Active ingredient(s): (Common name/s)	Manufacturer: (Name and address)	Minimum A.I.% purity	Maximum A.I. %purity

4. FORMULATION

4.1 Formulator: (Name)
Country and code:
Postal Address:
Physical address:
Office Telephone
Mobile:
Email address:

4.2 Internal code:

4.3 Composition (Information on composition may be attached in sealed envelope)

Ingredients and Function:	g/*l*	g/kg	Range

* Formerly GCPF

* SEARCH - Southern and Eastern African Regulation Committee on Harmonisation of Pesticide Registration

5. TOXICOLOGY (formulated veterinary pesticide)

5.1 Rat:	Acute Oral (LD_{50}* mg/kg)	Acute Dermal (LD_{50} mg/kg)	Inhalation **LC_{50} (mg/l/hour)
	Experimental	Experimental	Experimental

	Calculated	Calculated	Calculated
5.2 Rabbit:	Skin irritation	Eye irritation	
None			
Mild			
Moderate			
Severe			
5.3 Skin Sensitization in guinea pig: (tick)	None ☐ Mild ☐	Moderate ☐	Severe ☐

5.4 WHO classification:	Ia	Ib	II	III

a. Summary of other mammalian toxicological studies with references: eg. livestock, wildlife, poultry, pets	
5.6 Summary of environmental effects	
5.6.1 Toxicity to bees:	
5.6.2 Toxicity to fish and other aquatic organisms:	
5.6.3 Toxicity to birds:	
5.6.4 Toxicity to earthworms and soil micro-organisms:	
5.6.5 Toxicity to other non-target organisms:	
5.6.6 Persistence in environment:	
5.6.7 Other effects: Specify	
6. PACKAGING	
6.1 Packaging material or container:	
6.2 Pack size(s):	
6.3 Method of disposal of empty container(s):	
7. OTHER SPECIFIC REQUIREMENTS	
7.1 Operator exposure	
a). Dermal absorption.	
b). Likely operator exposure under field conditions	

c). Available toxicological data relating to other ingredients in formulation (non-active additives in formulation).
8. DECLARATION
For and on behalf of.....I,..... ..... hereby certify that the above mentioned information and data provided in support of this application is to the best of my knowledge true, correct and complete.

..... Name in full (printed)	..... Signature
..... Official Title	..... Date
Official Stamp of Applicant / Company	FOR OFFICIAL USE Remarks .... Signed: Date:

NOTE: The format of this application is recognized by all SEARCH countries.

*LD50=medium lethal dose

**LC50–medium Lethal Concentrate

GUIDELINE: ACTIVE INGREDIENT DOSSIER (OFFICIAL INFORMATION ONLY)

The dossier accompanying this form should provide details of the information requested on the methods used (physical and chemical), details of the methods used in and results of toxicological and ecotoxicological studies, methods of analysis etc. Numbering used in the dossier must correspond with that used in the application form.

ACTIVE INGREDIENT

1. DESIGNATION

REQUIREMENTS:	REMARKS:
1. DESIGNATION/IDENTITY OF A.I.	Specify accordingly.
1.1 Common name	
1.2 Manufacturer or Development code	

REQUIREMENTS:	REMARKS:
1.3 Source, Name and Address of manufacturer and address and location of manufacturing plants.	
1.4 Methods of manufacture(synthesis pathways)	
1.5 Chemical name (IUPAC)	
1.6 Chemical group	
1.7 Structural formula	
1.8 Empirical formula	
1.9 Patent status	
Is the A.I. under patent?	
Who is patent holder	
Expiry date	
1.10 Molecular mass	
1.11 CAS Number	

2. PHYSICAL AND CHEMICAL PROPERTIES

(active ingredient)

REQUIREMENTS:	REMARKS:
2.1 Physical state	Where relevant indicate method/test used.
2.2 Colour	
2.3 Odour	
2.4 Density at 20°C	
2.5 Vapour pressure at 20/25°C	
2.6 Volatility	
2.7 Hydrolysis DT_{50} ….. Days …… ^{0}C pH	Give the DT_{50} of the active ingredient, with mention of temperature and pH parameters employed during the determination.
2.8 Photolysis	Give the DT_{50} of the active ingredient (in days).
2.9 Solubility in water ……^{0}C ….. pH	Where relevant indicate method/test used.
2.10 Solubility in organic solvents	
2.11 n-octanol/water partition coefficient	
2.12 Boiling point ^{0}C	

2.13 Melting point ^{0}C	
2.14 Decomposition temperature ^{0}C	
2.15 Method of Analysis and Impurities	
2.16 Stability in water, hydrolysis rate, effect of light, identity of breakdown products	
2.17 Stability in organic solvents used in Formulation	
2.18 Stability in air; effect of light, identityof breakdown products	
REQUIREMENTS:	REMARKS:
2.19 Thermal stabilty, identity of breakdown product.	Where relevant indicate method/test used.
2.20 Flammability	
2.21 Flash point	
2.22 Explosive properties	
2.23 Oxidizing properties	
2.24 Absorption spectra – UV/Visible, infra-red, NMR, MS	
2.25 Reactivity towards container material	

3. TOXICOLOGY

(Active Ingredient)

Include a copy of an executive summary discussing ALL ISSUES named under Part3 or provide copies of the individual summaries from each study relating to issues mentioned under Part3. Information on the methods of testing must be provided.

REQUIREMENTS:	REMARKS:
ADI	Acceptable Daily Intake in mg product / kg body weight.
NOAEL	Non observable adverse effect level (NOAEL)(expressed in mg product / kg weight on animal)
Short term toxicity	
Oral cumulative toxicity (28 days study)	Not mandatory, but can be useful.

REQUIREMENTS:	REMARKS:
Sub-chronic toxicity test of 90-day duration.	Oral route on two species – one rodent(rat) and one non-rodent.
Dermal route – 28-days dermal, 90-days dermal.	Specify accordingly.
Inhalation route 28-days inhalation, 90-days inhalation.	Specify accordingly.
3.1 Eye irritation (rabbit)	
3.2 Skin sensitization (guinea pig)	
3.3 Reproduction (specify species)	
3.4 Subchronic toxicity 90 day NOAEL mg/kg/day	
3.5 Chronic toxicity NOAEL mg./kg/day	
3.6 Carcinogenicity (life time) NOAEL mg/kg/day	
3.7 Neurotoxicity NOAEL mg/kg/day	
3.8 Teratogenicity NOAEL mg/kg/day	
3.9 Mutagenicity /Genotoxicity	
3.10 Metabolism (rat)	
3.11 Other studies	Provide further information relevant to the toxicity profile of the product e.g. Toxicity of major metabolites, reaction or breakdown products of the pest control products formed in/or on treated plant/crop etc, which are likely to be consumed – in cases where different from those identified in animal studies. Toxic effects on livestock, poultry, pests etc. should be given.

4. ECO-TOXICOLOGY

Provide either an executive summary or individual summaries of studies on the behaviour of the veterinary pesticide in the environment. Provide information requested for in the application form.

REQUIREMENTS:	REMARKS:	
4.1 Birds (2 species)	LD_{50} mg/kg	Provide details of at least one land and one water bird, LD_{50} in mg product/kg bird weight and the NOAEL. Furthermore
	NOAEL	

REQUIREMENTS:	REMARKS:	
	LD_{50}mg/kg	provide information on the effect on reproduction.
	NOAEL	
	Reproduction	
4.2 Fish (2 species)	LD_{50} mg/kg	Provide details on at least two species studied, LC_{50} (in mg of product / litre of water) and the NOAEL. Furthermore provide information on the effect on reproduction. Indicate the bio-concentration factor (BCF) on the active ingredient in tissues.
	NOAEL	
	LD_{50} mg/kg	
	Reproduction	
	BCF	
REQUIREMENTS:	REMARKS	
4.3 Daphnia	LC_{50} mg/l	Specify and provide details on other organisms according to the information requested on the form.
	NOAEL	
4.4 Algae	LC_{50} mg/l	
	NOAEL	
4.5 Bees	LD_{50}µg/bee	
	NOAEL	
4.6 Earthworms	LC_{50} mg/kg	
4.7 Soil micro-organisms		

5. BEHAVIOUR IN ENVIRONMENT
(active ingredient)

Provide an executive summary or copies of summaries from each study relating to the issues highlighted in the application form.

REQUIREMENTS:	REMARKS:
5.1 Behaviour, ways of degradation, degradation products in soil:	Indicate the degradation path of the active ingredient in the soil and the degradation products formed.
5.11 Major metabolites	Specify the major metabolites in the soil and their behaviour.
5.12 DT_{50} (days)	Specify the half-life of the active ingredient in various types of soils.
5.13 Mobility of the A.I.	Specify the degree of mobility of the active ingredient in the soil hence leaching potential and possibility for ground water contamination. If high, provide details on further studies i.e. lysimeter study.

REQUIREMENTS:	REMARKS:
5.14 Adsorption	Indicate the degree of adsorption of the active ingredient in the soil.
5.15 Mobility of metabolites	Indicate the degree of mobility of the metabolites in the soil.
5.2 Behaviour, ways of degradation, degradation products in water:	Describe ways and speed of degradation of the active ingredient in water.
5.21 Major Metabolites	Specify the major break down products formed and their adsorption/desorption on sediments.
5.22 DT_{50} (days)	Specify the half-life of the active ingredient in water
5.23. Surface	Describe ways and speed of degradation in surface and ground water.
5.24 Ground	Provide an executive summary or copies of summaries from each study relating to the issues highlighted in the form.
5.3 Behaviour, ways of degradation, degradation products in air:	Describe ways and speed of degradation in air and break down products formed. (for fumigants and volatile products). .

7. RESIDUES

Provide either an executive summary or individual summaries of studies conducted concerning the issues listed in the application form.

REQUIREMENTS:	REMARKS:
7.1 Major metabolites	Provide either an executive summary or individual summaries of studies conducted concerning the metabolites in plants. . Specify the metabolites . State their toxicological effects.
7.2 Metabolism	Describe the principle of metabolization of the active ingredient in the plant and the degradation products formed.
7.3 Behaviour of residues	Indicate the action and the persistence of the metabolites in the animals.
7.5 MRL codex	MRL's (if available)

REQUIREMENTS:	REMARKS:
7..5.1MRL of country of origin	
7..5.2Proposed MRL	
7.9 Method of residue analysis	Provide a copy in the dossier for countries requiring it.

8. OTHER SPECIFIC REQUIREMENTS

REQUIREMENTS:	REMARKS:
8.1 Residue data from a GLP certified lab or as directed by the Directorate.	Provide an executive summary or copies of summaries from each study relating to residues.
8.2 Proposed withholding periods after use.	
8.3 Effects on taint, odour, taste or other quality aspects due to residues in or on fresh or processed products.	
8.4 Effects of industrial processing and/or household preparation on the nature and magnitude of residues.	

SUMMARY OF THE DATA SUBMITTED TO THE VMD FOR REGISTRATION OF A VETERINARY PESTICIDES

PART I

Trade Name.....

The Name and Address of Formulator.....

.....

Common Name of the active ingredient(s).....

Concentration of active ingredient(s).....

Source of active ingredient(s).....

Chemical Name.....

.....

Formulation type.....

Proposed Uses.....

.....

Packaging/Containers (Material size).....

.....

Registrant (Name, Address, Status).....

.....

Agents/Distributors in Kenya.....

.....

Premises (Reg. No. Date of issue) .....

PART II

CHEMISTRY DATA

a) Physical /Chemical Properties of the A.I.....

.....

.....

b) Physical/Chemical properties of the active ingredient (A1).....

.....

.....

.....

c) Composition of the veterinary pesticide (purity%, nature and content of impurities, isomers, by-products – other details should be provided in the dossier)

.....

.....

.....

d) Physical/Chemical Properties of the Formulated veterinary pesticide

.....

.....

.....

e) Composition of the Formulated veterinary pesticide (Concentration of A.I. in the formulation. other details should be provided in the dossier).....

.....

.....

f) Method of analysis for determination of the A.I. in technical and formulated veterinary pesticide.....

.....

PART III

Biological (efficacy) Data

a) Target Pest(s), Vectors, Diseases(s), Host(s). .....

.....

b) Method, Rate, Frequency of application.....

.....

c) Recommendations for use in Kenya .....

.....

d) Recommendations for use by authorized bodies outside Kenya.....

.....

PART IV

Toxicological data

a) Acute Toxicological Data of the active ingredient(s)

.....

.....

.....

b) Acute toxicity data of the formulated veterinary pesticide :..

.....

.....

.....

c) Short term toxicity studies.....

.....

d) Other toxicological studies:

1) Reproduction studies .....

.....

2) Teratological studies.....

.....

3) Neurotoxicity studies.....

.....

4) Mutagenecity studies.....

.....

5) Long term toxicity/carcinogenicity studies.....

.....

6) Accumulation of compound in tissues.....

.....

7) Metabolic studies.....

.....

8) Effects on animals .....

.....

9) Toxicity Data on impurities.....

.....

10) Toxicity Data on metabolites.....

.....

11) Human toxicology and medical aspects:

1) Hazards to humans.....

.....

2) Symptoms of poisoning.....

.....

3) Antidote.....

.....

4) First Aid Measures .....

5) Treatment .....

6) Safety Precautions/Restrictions.....

.....

.....

PART V – RESIDUE DATA

a) Principal Residues.....

.....

b) Disappearance and fate of residues.....

.....

.....

c) Method(s) of analysis (soil, water, feedstuffs etc.).....

.....

.....

PART VI

Environment and wildlife hazards

a) Degradation and mobility studies (soil, water, air) .....

.....

b)Toxicity to birds.....

.....

c)Toxicity to fish.....

.....

d)Toxicity to honeybees/beneficial insects.....

.....

e)Toxicity to earthworms, other soil invertebrates.....

.....

f)Changes in soil ecology.....

.....

PART VII

Information on Approvals/Registrations in other countries.....

.....

.....

.....

.....

.....

PART VIII

Draft of local label (paste)

.....

.....

PART IX

Brief prepared by.....

Signature.....

Official stamp .....

Date.....

PART X

Decision of the VMD technical committee

Recommended/Not Recommended for registration

Reasons:

.....

.....

Date.....

FORM C. 1 (r.27 (4))

REGISTER FOR VETERINARY MEDICINES

S/No	*Trade Name*	*Active Ingridient(S)*	*Reg. No*	*Class/ Category*	*Intended Use*	*Dosage Form*	*Manufac-Turer & Contact*	*Date Reg./Date Retained*

Form C. 2 (r.27(4))

REGISTER FOR VETERINARY PESTICIDES

S/No	Trade Name	Active Ingridient(S)	Reg. No	Class	Category	Function	Intended Use	Dosage Form	Manufacture R & Contact	Date Reg	Date Retained

FORM D 1 (r.23(3))

REPUBLIC OF KENYA

THE VETERINARY MEDICINE DIRECTORATE

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 .....

Approved name (in pharmacopoeia)

2. .....
3. Form of preparation .....
4. Active ingredient(s) and strength(s) .....
5. Condition(s) under which veterinary medicine is registered

   .....

   Name and business address of manufacturer.....

.....

Registered in the name of .....

Business address .....

6. Date of registration .....
7. Expiry date of registration.....

Date .....

Registrar of Veterinary Medicines

The Veterinary Medicines Directorate

FORM D.2 (r.23(3)

REPUBLIC OF KENYA

THE 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 .....
8. Business address .....
9. Date of registration .....
10. Expiry date of registration .....

Date .....

Registrar of Veterinary Medicines

The Veterinary Medicines Directorate

FORM E (r.24)

APPLICATION FOR RENEWALFOR RETENTION OF A VETERINARY MEDICINE/ PESTICIDE IN THE REGISTER

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

The Director

Veterinary Medicines Directorate

KABETE

Application number	
Name of applicant	
Address	
Registration number of veterinary medicine/veterinary pesticide for retention	
Declaration on GMP compliance	
Declaration on change on physical address if applicable	
Declaration of applicant that the registered veterinary medicine/ pesticide has not changed since registration/ previous retention	
FOR OFFICIAL USE	
Findings of pharmaco-vigilance	
Recommendations of the committee	
Approved/rejected (if rejected give reasons)	

Name .....

Signature..... Date .....

CEO, VMD

FORM F (r.47(2)(a))

REPUBLIC OF KENYA

THE 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 of .....as 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 .....

7. 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 G (r.47(2)(b))

REPUBLIC OF KENYA

THE 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 from .....located at..... in .....county and registered under.....

No.	*Veterinary medicine/pesticides*	*Category*	*Dosage form*	*Quantity*	*Reasons*

Impounding carried out in presence of:-

Name:.....ID .....Position in the business ..... Date:.....

Signature .....

Date.....

FORM H.1 (r.38(2)

APPLICATION FOR A PREMISES PERMIT FOR A VETERINARY PHARMACY

The Chief Executive Officer,

Veterinary Medicines Directorate

KABETE.

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.

1. Premise Location:

County:..... Town:.....

Road:.....Building:.....

2. Proposed category of vet medicine that will be traded in:
3. Other professionals working in this premise

No.	*Names*	*Position in the Business*	*Registration / enrollment no. new column qualification and experience*
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10			

Date .....Signature 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.

FORM H.2 (r.38(2))

APPLICATION FOR A VETERINARY WHOLESALEDEALERS PREMISES LICENCE

The Chief Executive Officer,

Veterinary Medicines Directorate

KABETE.

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.				

5.				
6.				
7.				
8.				

Signature of the Applicant .....Date .....

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 H.3 (r.38(2))

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

The Chief Executive Officer,

Veterinary Medicines Directorate

KABETE.

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. *(Please tick where applicable)*

☐ First Inspection ☐ Re – inspection after failure

☐ Routine Re- 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.....

Print Name.....

FORM I.1 (r.38(4)(a))

REPUBLIC OF KENYA

THE VETERINARY MEDICINE DIRECTORATE

PREMISES PERMIT FOR A VETERINARY PHARMACY

SERIAL NO . .....

Messrs. .....

of .....

Plot No..... is permitted to carry on business of 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

---

FORM I.2 (r38 (4)(b))

REPUBLIC OF KENYA

THE VETERINARY MEDICINE DIRECTORATE

VETERINARY WHOLESALEDEALERS PREMISES PERMIT

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 of .....KVB Reg. No.....(where applicable)

Date .....

Chief *Executive Officer,*

Veterinary Medicines Directorate.

NB: (*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 I.3 (r.38(4)(c))

REPUBLIC OF KENYA

THE 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 licenced 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 J (r. 37(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*

FORM K (r. 44(1))

APPLICATION FOR IMPORT/ EXPORT PERMIT FOR A VETERINARY MEDICINE

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

I. Name of Importer/Exporter.....

Address.....Tel. No.....Business Location.....

Land Reg.NO.....Street/Road.....Town.....

PIN NO.....VAT NO.....

Commodity.....Value (FOB) Kshs.....

Quantity .....Date of Manufacture.....Expiry Date.....

Purpose of Importation/Exportation.....

.....

Country of Origin..... Destination.....

Last Imports/Exports Quantity .....Value Kshs.....

Date.....

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

II. EVALUATION BY VETERINARY MEDICINES DIRECTORATE (VMD)

(a) The Directorate has evaluated the product.....and confirms that it is registered/not registered for .....under 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..

FORM L (r.44(2))

REPUBLIC OF KENYA

THE VETERINARY MEDICINE DIRECTORATE

PERMIT FOR IMPORTATION/ EXPORTATION OF A VETERINARY MEDICINE

CHIEF EXECUTIVE OFFICER

VETERINARY MEDICINES DIRECTORATE

KABETE

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. .....

This permit is not transferable to any other person without the approval of the Directorate.

NB This permit is valid for one consignment only, for three (3) months from the date of issue.

FOURTH SCHEDULE (r.17)

CODE OF CONDUCT FOR MEMBERS OF AND EMPLOYEES OF THE DIRECTORATE

Impartiality and independence of members

1. (1) Every member and employee of the Directorate shall impartially and independently perform the functions of a member in good faith and without fear, favour or prejudice, and without influence from–

(a) the National or County Government;

(b) any public officer;

(c) any political party;

(d) any candidate participating in an election; or

(e) any other person or authority.

Independence from political or public office.

2. (1) A member or employee of the Directorate shall not, during tenure of office, be eligible for—

(a) appointment or nomination to a political office; or

(b) appointment to another public office.

(2) A member of the Directorate may not–

(a) by their membership, association, statement, conduct or in any other manner place in jeopardy the perceived independence of the member, or in any other manner harm

the credibility, impartiality, independence or integrity of the Directorate;

(b) make private use of or profit from any confidential information gained as a result of being a member of the Directorate; or

(c) divulge any information to any third party, save in the course of official duty.

Disclosure of conflicting interests.

3. (1) If a member or an employee is directly or indirectly interested in any contract, proposed contract or other matter before the Council and is present at any meeting of the Council at which the contract, proposed contract or other matter is the subject of consideration, the member or employee shall, at the meeting and as soon as practicable after the commencement thereof, disclose the fact and shall not take part in the consideration or discussion of, or vote on, any questions with respect to the contract or other matter or be counted in the quorum of the meeting during consideration of the matter.

(2) A member or employee whose personal interest conflicts with their official duties shall–

(a) declare the personal interests to their supervisor or other appropriate person or body in writing and comply with any directions given to avoid the conflict; and

(b) refrain from participating in any deliberations with respect to the matter.

(3) No member of staff of the Directorate shall transact business with the Directorate directly or indirectly.

Professionalism

4. A member or employee of the Directorate shall–

(a) perform their duties in a manner that promotes and maintains public confidence in the Directorate;

(b) treat the public and colleagues with courtesy and respect;

(c) discharge all their duties in a professional, timely and efficient manner and in line with the rule of law; and

(d) respect the rights and freedom of all persons that he may interact with.

Improper enrichment.

5. A member or employee of the Directorate shall not–

(a) use their office or organization to improperly enrich themselves or others;

(b) accept or request gifts or personal favours from any person who may have a commercial interest with the Directorate or any other interest that may be affected by the normal business of the Service; or

(c) use information that is acquired during the course of their duties or connected to their duties for their benefit or for the benefit of others

Integrity in private affairs.

6. A member or employee shall conduct their private affairs in manner that maintains public confidence in the integrity of their office and the Directorate as a whole and shall—

(a) not evade paying taxes;

(b) not neglect their financial obligations;

(c) submit an annual declaration of their income, assets and liabilities to the Commission responsible for such declarations from public officers;

(d) not engage in political activity that may compromise or be seen to compromise the neutrality of their office, or the Directorate; and

(e) not preside over or play a central role in the organization of a fundraising activity.

Sexual harassment.

7. (1) A member or employee shall not sexually harass a member of the public or colleague.

(2) Sexual harassment includes –

(a) making a request or exerting pressure for sexual activity or favours;

(b) making intentional or careless physical contact that is sexual in nature; or

(c) making gestures, jokes or comments, including innuendoes regarding another person's sexuality.

Nepotism.

8. A member or employee shall not practice favouritism on the grounds of tribe, race, kin, culture, sex or acquaintance or otherwise in performance of their duties.

Application of the Public Officers Ethics Act.

9. This Code is in addition to the provisions of the Public Officers Ethics Act and where there is a conflict between the Code and these Regulations, the provisions of the Act shall prevail.

Breach of code.

10. Any breach of the Code by a member or officer of the Service shall be treated as gross misconduct.

FIFTH SCHEDULE (r. 24(3), 38(5) & 61)

FEES

Purpose	*Fees*	*Frequency*
Application forms under these regulations shall be issued free of charge		
Inspection fee: (i) Retail Veterinary Pharmacy	Kshs 15,000	Once
Inspection fee: (ii) Wholesale Veterinary Pharmacy	Kshs 30,000	Once
Good Manufacturing Practice inspection per		

site		
1) Local manufacturing site.	Kshs 100,000	Every three (3) years
2) Foreign manufacturing site	USD 4,000	Every three (3) years
Product registration fees per imported veterinary medicine	USD 1,000	Once
Product registration fees for locally manufactured veterinary medicine	USD 500	Once
Appeals for rejected application for registration of veterinary medicine	USD 300	
Retention of veterinary medicine in the register	USD 300	Annually
Veterinary pharmacy practice fee:		
1) Wholesaler	Kshs 30,000	Annual
2) Retailer	Kshs 10,000	Annual
Manufacturer fee	Kshs 30,000	
Import permit	Kshs 1,000	Per consignment
Inspection/verification fee	0.75% of the consignment value	Per FOB consignment
Advertisement per veterinary medicine	Kshs50,000	Annual
Fees for duplicate permit or licence	Kshs 1,000	Per copy

Made on the 19th August, 2015.

ADAN MOHAMED,
Cabinet Secretary for Agriculture, Livestock and Fisheries.

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EXPLANATORY MEMORANDUM

EXPLANATORY MEMORANDUM TO THE VETERINARY SURGEONS AND VETERINARY PARAPROFESSIONALS ACT (THE VETERINARY MEDICINES DIRECTORATE) REGULATIONS, 2015

PART I

Name of the Statutory Instrument:	**The Veterinary Medicines Directorate Regulations, 2015**
Name of the Parent Act:	**The Veterinary Surgeons and Veterinary Paraprofessionals Act, Number 29 of 2011**
Enacted Pursuant to:	**Section 39 (2) (a) of the Act**
Name of the Ministry/Department:	**Ministry of Agriculture, Livestock and Fisheries/The Kenya Veterinary Board**
Gazetted on:	**16th October, 2015**
Tabled on:	**29th October, 2015**

PART II

1. Purpose of the Statutory Instrument

1.1 The Veterinary Medicines Directorate Regulations transfer the regulation of veterinary medicines from the Pharmacy and Poisons Board which is a state corporation under the Ministry of Health to the Veterinary Medicines Directorate, a new institution under the Ministry of Agriculture, Livestock and Fisheries. The move will improve efficiency of regulatory controls over the manufacture, importation, exportation, use, inspection and monitoring of veterinary medicines. This will ensure prudent use of veterinary medicines and control the present misuse which is having negative consequences on animals, humans and the environment.

2. Legislative Context

2.1 The Veterinary Medicines Directorate Regulations are implementing the provisions of section 39 (2) (a) of the parent Act which is a fairly new Act that was enacted upon the repeal of the Veterinary Surgeons Act, Chapter 366. The Regulations further domesticate international standards in the regulation of veterinary medicines and products as set out in Article 3.4.11 of Chapter 3.4 of the Terrestrial Animal Health Code of the World Organization for Animal Health (www.oie.int/). The Regulations will supercede relevant regulations in the Pharmacy and Poisons Act, Chapter 244.

3. Policy Background

3.1 The Veterinary Medicines Directorate Regulations implement part 3.4.8 of Sessional Paper Number 2 of 2008 for the National Livestock Policy which noted that there was inadequate control of veterinary medicines under the existing National Drugs Policy and the Pharmacy and Poisons Act, Chapter 244, both measures being housed in the Ministry responsible for human health. The weakness had led to misuse of veterinary medicines and caused harm to animals and to consumers of animal products.

In debating the Sessional Paper Number 2 of 2008 in Parliament, vide the Hansard of 2.30 pm on 3rd December 2008, the Ministry responsible for health, which was represented by the Assistant Minister, acknowledged the existence of the regulatory gap and further supported the motion, advising that the draft under debate be improved to include the human element as well as a distribution system for veterinary medicines. Parliament approved the policy and provided that the government would separate the management of veterinary drugs from that of human drugs and the control and regulation of veterinary drugs would be moved to the Ministry responsible for livestock affairs. This is what the Veterinary Medicines Directorate Regulations have achieved.

The same Sessional Paper Number 2 of 2008 in part 4.1.4 also noted legal weaknesses and gaps in the Veterinary Surgeons Act, Chapter 366, with deficiency in regulation of veterinary technicians, the training in veterinary medicine and in the control of veterinary medicines and poisons. A direction to comprehensively review the Veterinary Surgeons Act was provided in part 3.4.2 of the Sessional Paper. This was done in 2011. A new Act, the Veterinary Surgeons and Veterinary Paraprofessionals Act, Number 29 of 2011, was enacted and which covers a wider scope as detailed in the preamble, specifically to regulate the veterinary profession and also to "provide for matters relating to animal health services and welfare". Veterinary medicines are integral components of animal health services and welfare and their proper control as provided in the Veterinary Medicines Directorate Regulations would implement the objective of the Act.

A wide stakeholder consultation process has been undertaken as detailed in section 4 of this Memorandum. The veterinary and animal-owning fraternity welcomed the move and was impatient for its successful conclusion. The Pharmacy and Poisons Board was also in agreement on the need for the veterinary sector to take control of the regulation of veterinary medicines and were only concerned with the structure of doing so. Pharmacists under the umbrella of Pharmaceutical Society of Kenya expressed opposition to the Regulation, citing their professional status.

The concerns raised by pharmacists need greater elaboration. Many of the active ingredients comprising veterinary medicines are also used in human medicine and some also in crop production. They have multisectoral ownership and responsibility, with the debate being which profession is best placed to regulate which aspects of the medicines. Granted, pharmacists are effective professionals in the extraction and compounding of medicines including veterinary medicines, an activity which is regulated by government but implemented by the private sector. Veterinary professionals, on their part, are effective

professionals in the healing and poisoning aspects of veterinary medicines, including prescription, dispensing, distribution, inspection, validation, monitoring and supervision. The lead profession in the matter appeared to be the issue in the concerns of pharmacists, a question that had already been answered by Parliament through enacting the Sessional Paper Number 2 of 2008 and the Veterinary Surgeons and Veterinary Paraprofessionals Act. For the regulation of veterinary medicines, the lead profession is the veterinary profession. However, a link was established in the Regulation by incorporating the Registrar of the Pharmacy and Poisons Board in the management organ of the Veterinary Medicines Directorate.

4. Consultation outcome

4.1 Methodology

Consultation on the proposed Regulations utilized **3** procedures, i.e. stakeholder workshops, written submissions and expert meetings. **7** email submissions were made while there were **4** experts meetings under the auspices of the Procedures, Rules and Regulations Committee of the Kenya Veterinary Board in which experts in veterinary medicines from the University of Nairobi and from the pharmaceutical industry were incorporated. **5** stakeholder workshops were held in March and April 2014 in Mombasa, Kisumu, Nakuru, Embu and Nairobi where **301** persons participated. The profile of participants in consultative fora is analyzed hereunder.

Profile of participant in consultative fora

	Sector				
	Animal health	**Farming & processing**	**Chemist & pharmacy**	**Development partners**	**Media**
Nairobi	89	6	25	2	7
Kisumu	42	3	3	2	0
Nakuru	40	3	3	1	0
Mombasa	31	3	1	0	0
Embu	37	2	0	1	0
Sub-total	**239**	**17**	**32**	**6**	**7**
Email submissions	**7**				
Experts	**8**				

4.1 Analysis of comments

53% of comments were on editorial and technical improvement, **41%** on the scale of the proposed fees and **6%** on composition of the management organ of the Directorate. **80%** of

the suggestions were adopted in the draft while **20%** were ignored after due consideration, as analyzed hereunder.

Issue	Number of comments	Comments adopted in draft	Comments not adopted in draft	Reasons
Suggested editorial and technical improvements	60	45	15	The ignored comments were either due to participants being unclear on draft clauses or had inadequate information on the policy and international standards which were the foundation to the draft
Suggested composition of the management organ to include gender, integrity and representation of advocacy groups	7	5	2	Representation of advocacy groups was rejected as the management organ would not be independent; advocacy groups were otherwise allowed to nominate a list of candidates from which Kenya Veterinary Board would pick names and forward to Cabinet Secretary.
Scale of fees perceived as too high	46	40	6	Scale of fees was adjusted downwards or left as in Cap 244; the report of Presidential Task Force on State Corporations, page 80, (advising that regulatory bodies could raise their own funds and not depend on exchequer), was considered in resisting some of the extreme suggestions in reduction of proposed fees

5. Guidance

5.1 The Veterinary Medicines Directorate Regulations is not a legally complex instrument. However, veterinary medicines inspectors will undergo training on their procedures which will be prescribed by Kenya Veterinary Board. The instrument will also be publicized through the websites of the parent Ministry, the Kenya Veterinary Board and of the various veterinary professional and paraprofessional associations. It will also be deposited in the Ministerial and Veterinary Department libraries. It is also expected that the Government Printers will as usual avail it for procurement by members of the public.

6. Impact

6.1 The Impact on Fundamental Rights and Freedoms

The application of the Veterinary Medicines Directorate Regulations will not have any adverse impact on the enjoyment of the fundamental rights and freedoms as set out in the Constitution. Rather, the Regulations will enhance the enjoyment of economic and social rights under Article 43, especially the right to adequate food of acceptable quality and the right to the highest attainable standard of health. The Regulations also uphold the consumer interests provided in Article 46 on their right to goods and services of reasonable quality as offered by public entities and the rights to the protection of their health, safety, and economic interests.

6.2 The Impact on the Private Sector

The private sector would incur the costs of additional licenses, certificates and fees and of the time spent on inspection and in the approval process. The parent Act in section 45 (2) (f) empowers the Cabinet Secretary, through regulation, to charge such fees. However, overall the society would benefit from the expenditure as the cost/benefit analysis in section 4 of the attached Regulatory Impact Assessment demonstrated, with great benefits in the areas of improved animal and human health and better livestock productivity. There would be better performance of legitimate veterinary medicine businesses as quacks and counterfeit medicines are curtailed. A transition period has been provided to enable existing licenses, certificates and permits to continue operating until their validity period expires before applying for retention or renewal under the new regulations.

6.3 The Impact on the Public Sector

Implementation of Veterinary Medicines Directorate Regulations would occasion expenditure of public funds, either as voted funds or Appropriation in Aid. However, overall the society would benefit from the expenditure as demonstrated by the cost benefit analysis.

6.4 Regulatory Impact Assessment

A full Regulatory Impact Assessment was conducted on the instrument and is attached to this Memorandum.

7. Monitoring and review

7.1 The regulatory performance of the Veterinary Medicines Directorate will be monitored after every 12 months through reports. An ex-post impact assessment will be carried out after 5 years and the legislation may be amended accordingly.

8. Contact

8.1 Dr. B. Odhiambo Godia, Ag. Chief Executive Officer of the Kenya Veterinary Board
Tel: +254 722 305 253 or email: info@kenyavetboard.org can answer any questions regarding the Statutory Instruments Act requirements.

VETERINARY MEDICINES DIRECTORATE REGULATIONS, 2015

REPORT OF REGULATORY IMPACT ASSESSMENT

By

Kenya Veterinary Board,
P.O. Box 513-00605 Nairobi

1. Introduction

The Assessment was done ex-ante for the purpose of estimating the consequences of the Veterinary Medicines Directorate Regulations to animal and human health and welfare as well as the impacts to the veterinary medicines industry players. Regulation is a public governance tool which imposes standards and limits that have benefits and costs to individuals and the general members of the society and to the environment. For veterinary medicines, regulation would impose costs of doing business and also costs of the approval process for the products themselves and of running inspectorate and monitoring systems. Members of the society would benefit from improved health and welfare of animals and humans, greater animal productivity and a more sustainable environment. The findings of such an assessment enable the government to formulate rational regulations which assure greater benefit to the industry and society as compared to the costs of compliance.

The Assessment was carried out as guided to the procedures set in the ***Statutory Instrum Act, Number 23 of 2013***. The Kenya Veterinary Board secretariat prepared the assessment based on data and information in published literature on the subject matter and augmen inputs from workshop-based, online and internet structured consultation with stakeho draft report was published as ***Gazette Notice*** Number 9023 on 19th December 2014 the ***Daily Nation*** of 24th December 2014 and a two-week period given for public er comments. This final report was thereafter compiled taking into consideration comments from stakeholders.

The report comprises an assessment of three options with regard to the reg medicines. Option 1 is regulation through the Veterinary Medicines Direc retaining of the status quo whereby the regulation is carried out by the Board under the Ministry of Health. The Third Option is self-regulatior

2. Objectives of the legislation and the reasons for them

The Veterinary Medicines Directorate Regulations has the obj of veterinary medicines by the animal health sector from t hitherto been running the service through the Pharmacy a Laws of Kenya. The transfer was found necessary as the l regulating veterinary medicines so as correct the prevail with negative consequences in the health and w environment. The undesirable situation in the serv

enunciated by National Assembly in section 3.4.8 of the **Sessional Paper Number 2 of 2008 on National Livestock Policy**. The legal framework for the transfer was granted by the National Assembly in section 39 (2) (a) of the **Veterinary Surgeons and Veterinary Para-professionals Act, Number 29 of 2011.**

The and the use of veterinary medicines by unqualified persons in animal treatment lead to incorrect use resulting in delayed or failed healing, toxicity to animals and also increases costs of managing animal diseases to the farmer. The mishandling of veterinary medicines in animal production also leads to the development and promotion of resistant pathogenic microorganisms rendering common animal diseases either incurable or more costly to treat with other reserved medicines. Such resistant pathogens also get into the environment and into human food leading to human diseases that are incurable or more costly to treat. Further, the mishandling would also cause the entry of undesirable levels of residues of veterinary medicines in animal-derived human food leading to direct poisoning or exacerbation of the development of resistant human pathogens and loss of access to markets for the so-contaminated animal-derived food and feed. The legislation would enhance the capacity and institutional framework to assure that veterinary medicines are registered and used in accordance with veterinary professional and scientific norms and that the risks of entry of residues and resistant pathogens is curtailed.

3. The effect of the legislation, including the effect on the operation of the Pharmacy and Poisons Act

The Veterinary Medicines Directorate Regulations would have the effect of establishing a veterinary institution, called Veterinary Medicines Directorate, to be charged with appro veterinary medicines and their distribution systems, the supervision of the use of such m in animal therapeutics and the running of inspectorate and monitoring systems so as that the objectives of the regulation is being achieved. The legislation would su veterinary drugs aspects in the Pharmacy and Poisons Act, Chapter 244, based provisions of the government policy and law as elaborated in statement 2 above and human health sector would be expected to continue with the regulation drugs except veterinary medicines and will have a formal linkage with the through their representation in the management organ of the new veter Pharmacy and Poison Rules (i.e. Legal Notices L.N. 186/1957, L.N. 44 L.N. 426/1958, L.N. 498/1958, L.N. 550/1959, L.N. 114/1960, L.N. L.N. 631/1963, L.N. 92/1964, L.N. 365/1964, L.N. 115/1968, L.N L.N. 41/1971, L.N. 120/1984, L.N. 51/1985, L.N. 61/2002, L.N. 91 superseded by the Veterinary Medicines Directorate Regulati regulation of veterinary medicines, with a transition period bei and licensure to expire within their specified time. The by Pharmacy and Poisons Board to veterinary m Poisons Act will thence be paid to the new vet and quantity, but it is expected that efficie institution.

4. An assess of the costs and benefits of the Veterinary Medicines Regulations and of other to achieve the same objective.

The purpose of this step in the Assessment is to establish quantitatively whether the benefits from the new regulatory system are justified as compared with the expected costs of the intervention. The intervention would be adjudged economically worthwhile if the benefits would exceed than the costs.

a) Methodology used

An ex-ante cost-benefit analysis was carried out and was based on the additional costs and benefits of the intervention in the period of 10 years provided in the ***Statutory Instruments Act***. The costs and benefits streams were identified using the partial analysis itemization in ***Table 1***, namely the costs saved and the expected revenue from the intervention forming the benefits stream and the extra costs of regulation and revenue forgone by stakeholders as costs stream.

Table 1: Parameters for benefits and costs streams

Benefits stream	
Costs saved	1. Savings in costs of higher-level treatment for infections with resistant organisms in humans.
	2. Savings in costs of higher-level treatment for infections with resis organisms in animals.
	3. Costs saved of mortality in resistant human cases.
	4. Costs saved in wasted veterinary medicines through misclassif therapy.
Extra revenue	5. Extra earning from improved animal productivity.
Costs stream	
Extra costs	1. Staff salaries
	2. Allowances
	3. Stationary
	4. Utilities
	5. Office maintenance & renovations
	6. Vehicle procurement, operation & mainte
	7. Office equipment sets
	8. Management costs for additional c
	9. Fees for new or additional licens industry

0. Reduction in slaughtered culls: cattle, sheep, goats

Revenue fo

s in the benefit and cost streams were estimated from published literature and the present situation in Kenya. Additional data was sourced through structured interview with stakeholders. The values were discounted using the present Central Kya Discount Rate Window (i.e. 14.5%). These data sources were used to build a igh which the Present Value of Benefits (PVB), the Present Value of Costs (PVC), resent Value (NPV), the Benefit/Cost Ratio (BCR) and the Internal Rate of Return r the intervention were estimated for the 10 years envisaged in ***Statutory Instruments*** nsitivity analysis was also done to determine the drivers of the results from the model and ecision of the findings.

The three options (VMD Regulations, Status-Quo, and Self-Regulation) were considered with respect to the analysis of benefits and costs and recommendations made.

(b) Assumptions and important notes made in the analysis

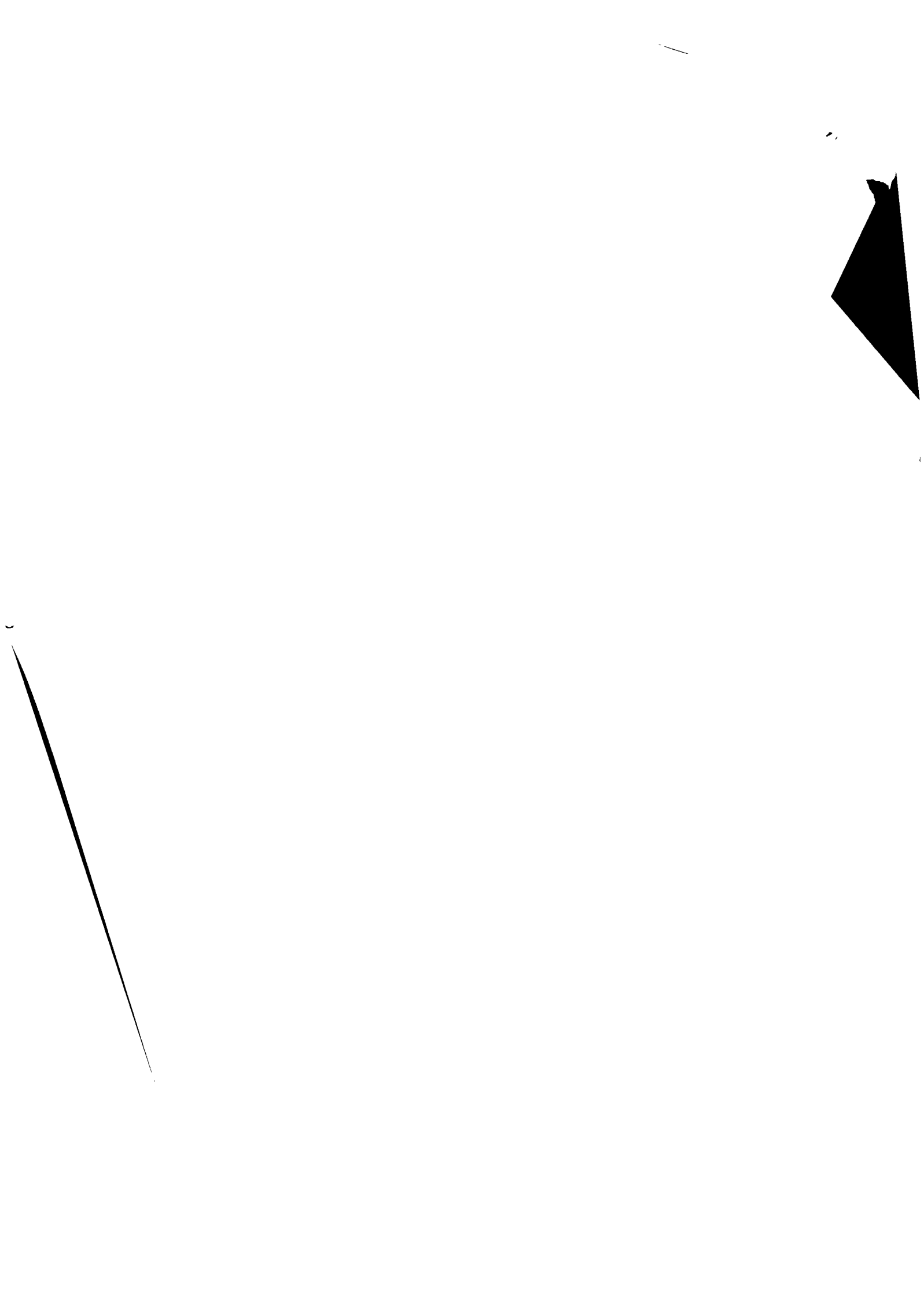
The analysis made a number of assumptions as detailed hereunder:

(i) The benefits and costs of the intervention would be reflected in the management of veterinary antimicrobial medicines and the outcomes of their regulation and use. The VMD Regulations will impact most on the regulation of prescription-only antimicrobial medicines whereby the control of their distribution, dispensing and use will be enhanced.

(ii) Veterinary pest control products, antihelmintics, antiseptics and disinfectants are ordinarily dispensed over-the-counter. There would be benefits and costs arising from the general application of pharmacovigilance, which were not assessed, but the dispensing system would continue unchanged by the intervention. Similarly, benefits and costs concerning the regulation of veterinary analgesic, anaesthetics and hormones were not assessed as these medicines are usually used in low quantities and are largely restricted to veterinary surgeons, which would continue unchanged by the intervention.

(iii) Globally, 50-80% of the quantity of all antimicrobial medicines are used in animal farmi and their handling and performance affects animal health directly, and human he indirectly, through treatment success or failure, acute or chronic poisoning encouragement of development of resistant in microorganisms, morbidities and mor the value of which can be, and was, estimated in the Assessment.

(iv) A number of pathogenic organisms are the main drivers of the use of an medicines both in animal and human health, namely agents for non-typhoidal sa and the agents for tuberculosis, *Streptococcus species* pneumonia, *Escl* infections, *Staphylococcus aureus*, *Klebsiella pneumonia,* and *Campylol* infections. These agents cause respiratory and enteric infections in animals a also feature greatly in bovine mastitis. Benefits and costs in the mana



antimicrobial medicines were assumed to be a good indicator of the overall organism act of the intervention.

(vi) It is assumed that resistant microorganisms getting to humans originate from the animal industry. Whereas large proportions of such microorganisms indeed originate from animals, others enter human systems from the environment while others circulate within the human community.

It is assumed that misuse of antimicrobial medicines occurs only within the animal industry. This is not necessarily the case as misuse in the form of under- and over-prescription also occurs within the human health sector.

(vii) The number of infections with the target agents and the animal and human population data was assumed to remain the same during the intervention period; however, the number of cases would naturally be more or less after intervention and populations would increase.

(viii) The quality and quantity of the available data was limited whereas the estimation knowledge was good. Therefore, the results should be considered adequate for understanding the veterinary medicines regulatory system and as an aid in decision-making on the regulatory policies but the results would be fairly constrained as a representation of the actual prediction of future outcomes.

(ix) It is assumed that there will not be any benefits in Year 0 of VMD regulation (i.e. present year 2015) except for savings from veterinary medicines otherwise wasted o misclassified therapies. Costs would start being incurred in Year 0 while the rest benefits will start being realized in Year 1.

(c) Results

(i) Option 1

The results for Option 1, the VMD Regulations, are shown in ***Table 2(a)*** and ***Ta*** summary is as hereunder:

Present Value of Benefits (PVB) = Ksh 709,216,024,282/=

Present Value of Costs (PVC) = Ksh 106,771,272,449/=

Net Present Value (NPV) = Ksh 602,444,751,833/=

Benefit/Cost Ratio (BCR) = 6.6

From the findings, the NPV was much > 0 and the BCR muc implementing the VMD Regulations, the society would ber intervention is worthwhile.

Sensitivity analysis gave favourable results. When the benefits stream in the model was reduced by costs increased by 50%, the BCR was 2.21. Similarly, the results remained positive benefits and halving the benefits still gave a positive result of BCR 1.7. The converse, Do from the results of the model were sufficiently robust.

alues of each of the parameters were halved to determine which of them had the greatest ence on the BCR. The costs of rearing the additional animals had the greatest influence CR =11.7), followed by the costs saved from human deaths due to antimicrobial resistance (BCR =3.8).

of 1.31 when there was 67% reduction in benefits and 67% increase in costs.

The Internal Rate of Return was not calculated for the reason that costs exceeded benefits only in the first year and therefore its results would be misleading.

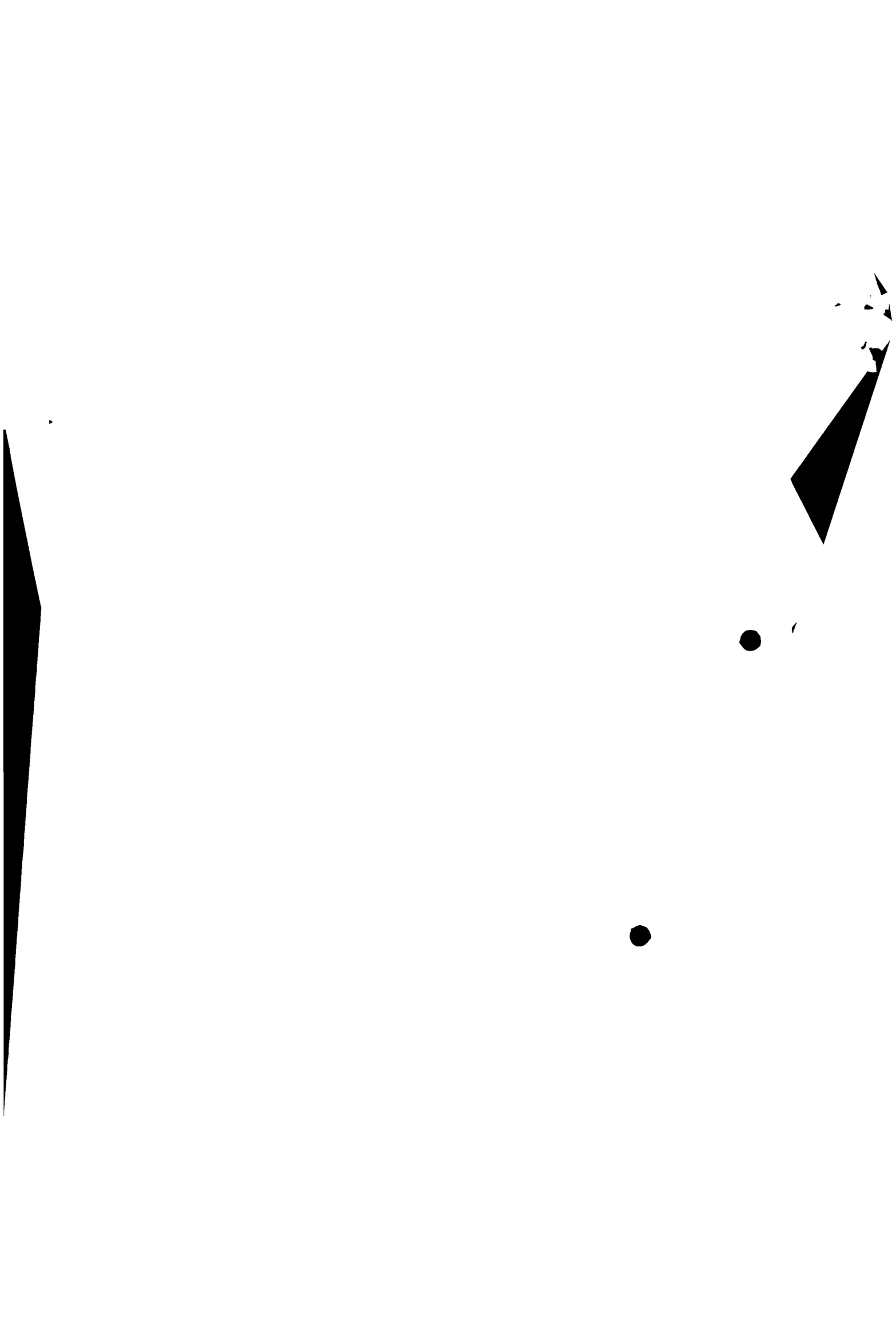
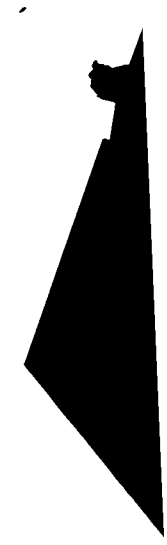


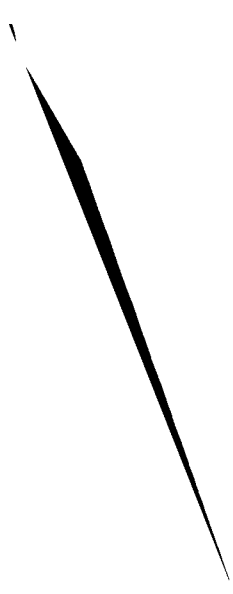
Table 2(a): Benefits analysis of VMD Regulations/Ksh

	BENEFIT STREAM						
Year	**Costs saved in higher-line treatment of humans**	**Costs saved in higher-line treatment of animals**	**Extra earning from improved animal production**	**Costs saved of mortality in resistant human cases**	**Costs saved from misclassification of therapy**	**Total Benefits**	**Discoun... efits (Rate = 14.5%,**
0	0	0	0	0	3,501,750,000	3,501,750,000	3,501,750,000
1	6,311,031,447	5,896,183,083	5,248,466,462	124,319,595,400	3,501,750,000	145,277,026,392	126,879,499,032
2	6,311,031,447	5,896,183,083	5,248,466,462	124,319,595,400	3,501,750,000	145,277,026,392	110,811,789,548
	6,311,031,447	5,896,183,083	5,248,466,462	124,319,595,400	3,501,750,000	145,277,026,392	96,778,855,500
	6,311,031,447	5,896,183,083	5,248,466,462	124,319,595,400	3,501,750,000	145,277,026,392	84,523,017,904
	...31,447	5,896,183,083	5,248,466,462	124,319,595,400	3,501,750,000	145,277,026,392	73,819,229,611
		5,896,183,083	5,248,466,462	124,319,595,400	3,501,750,000	145,277,026,392	64,470,942,892
		...183,083	5,248,466,462	124,319,595,400	3,501,750,000	145,277,026,392	56,306,500,342
			5,248,466,462	124,319,595,400	3,501,750,000	145,277,026,392	49,175,982,831
			...466,462	124,319,595,400	3,501,750,000	145,277,026,392	42,948,456,621
				...18,876,358,600	35,017,500,000	1,310,994,987,528	**PVB=709,216,024,281**

Table 2(b): Costs analysis of VMD Regulations/Ksh

Year	COSTS STREAM											
	Salaries	Allowances	Stationary	Utilities	Office maintenance & renovations	Vehicle, operation & maintenance	Office equipment sets	Management costs for additional cattle, sheep, goat, poultry	Slaughtered culls: cattle, sheep, goats	New fees	Total costs	Discounted Costs (Rate = 14.5%)
0	48,410,880	52,215,000	4,646,000	828,000	9,524,760	111,136,000	2,401,200	16,141,903,600	5,612,800,000	170,017,500	22,109,506,300	22,109,506,300
1	48,410,880	52,215,000	4,646,000	828,000	9,524,760	31,096,000	0	16,141,903,600	2,918,656,000	170,017,500	19,332,921,100	16,884,647,249
2	48,410,880	52,215,000	4,646,000	828,000	9,524,760	31,096,000	0	16,141,903,600	1,517,701,120	170,017,500	17,931,966,220	13,677,821,720
	48,410,880	52,215,000	4,646,000	828,000	9,524,760	31,096,000	0	16,141,903,600	789,204,582	170,017,500	17,203,469,682	11,460,394,997
	880	52,215,000	4,646,000	828,000	9,524,760	31,096,000	0	16,141,903,600	410,386,383	170,017,500	16,824,651,483	9,788,679,971
		52,215,000	4,646,000	828,000	9,524,760	31,096,000	0	16,141,903,600	213,400,919	170,017,500	16,627,666,019	8,448,971,776
		00	4,646,000	828,000	9,524,760	31,096,000	0	16,141,903,600	110,968,478	170,017,500	16,525,233,578	7,333,557,251
			646,000	828,000	9,524,760	31,096,000	0	16,141,903,600	57,703,609	170,017,500	16,471,968,709	6,384,209,085





8	48,410,880	52,215,000	4,646,000	828,000	9,524,760	31,096,000	0	16,141,903,600	30,005,876		
9	48,410,880	52,215,000	4,646,000	828,000	9,524,760	31,096,000	0	16,141,903,600	15,603,056	170,01	
Total	484,108,800	522,150,000	46,460,000	8,280,000	95,247,600	391,000,000	2,401,200	161,419,036,000	11,676,430,023	1,700,175,000	44,270,976
										175,3	8,156

5,566,352,832	
4,857,185,594	
PVC=	
106,771,272,449	

(ii) Option 2

In Option 2 the Status Quo is maintained. There are neither additional costs nor additional benefits for the option. As such, the NPV = 0 and the BCR = 1. Every shilling spend under Option 2 would earn benefits equivalent to one shilling.

(iii) Option 3

In Option 3 the industry self-regulates on veterinary medicines and the government, either through Regulations or the Pharmacy and Poisons Act, divests from regulating veterinary medicines.

Option 3 is a very hypothetical scenario, unless in regions with complete breakdown of government functions where it might apply. Veterinary medicines and indeed all medicines are public human and animal health goods, meaning that the user gains benefits which also benefit non-users in the society non-exclusively and in non-rivalry manner. Conversely, a misused medicine harms not just the user or his animals but also harms the rest of the society and their animals. Governments are formed with a central obligation to promote and protect social welfare, which includes assuring animal and human health and welfare. This obligation is upheld in all international treaties as in national law. For example, the Constitution of Kenya in Article 43 recognizes these social welfare needs as rights and fundamental freedoms and require government to provide them. Governments legitimately taxes citizens to finance the provision these social welfare services.

The Assessment did not come across information of any country in the world where vet medicines are managed through industry self-regulation. On the contrary, there wa information where many governments regulate veterinary medicines. Nevertheless, th and costs under Option 3 were assessed. The assumptions under the self-regulation that the involvement of government would be minimal and it would not levy licer Industry would be expected to develop voluntary or firm-own codes of practic medicines and run management boards to supervise or enforce these codes. Com would drive the process with little or nil involvement or accountability to would be multiplicity of rules as standards would be expected to vary with p and this would render adjudication difficult except probably through p multiplicity might provide a benefit if innovative approaches emanate present example of such innovation to assist in the analysis. Sanctions would be limited to the particular code or business and would occur third parties has already been compromised; penal sanctions wo system.

The parameters for partial analysis of Option 3 are set out in ***Table 3***.

Table 3: Benefits and costs streams for Option 3

	Costs of government licenses and fees
...nue	Benefits of (any) innovative approaches to regulation
Team	
costs	Management boards costs: allowances, equipment and office space
	Losses through misclassification of therapy
Revenue forgone	Nil

The model for Option 3 gave the following results in ***Table 4 (a)*** *and* ***Table 4 (b).*** The summary is as hereunder:

Present Value of Benefits (PVB) = Ksh 5,418,385,637/=

Present Value of Costs (PVC) = Ksh 20,908,370,902/=

Net Present Value (NPV) = Ksh -15,489,985,266/=

Benefit/Cost Ratio (BCR) = 0.259

From the findings, the NPV was much < 0 and the BCR was much < 1. For every 1 shilling spent on implementing the industry self-regulation, the society would benefit with less than a shillings. Therefore, the intervention is not worthwhile.

Sensitivity analysis also gave unfavourable results. When the benefits stream in the model w reduced by 50% and costs increased by 50%, the BCR was 0.09. Similarly, the results were B of 0.05 when there was 67% reduction in benefits and 67% increase in costs. Doubling benefits and halving the costs gave BCR 1.029 which is a very weak feasibility, whi converse gave BCR 1. This outcome confirms that the conclusion from the results of the were fairly robust.

As with Option 1, the values of each of the parameters were halved to determine whi had the greatest influence on the BCR and it was the costs of misclassification of th = 0.509) followed by saving on government licensing and permits (BCR = 0.13).

(d) Conclusion

The analysis of benefits and costs indicated that, within the scope of the as applying the VMD Regulations is economically worthwhile and gives the bes

sted (BCR = 6.7) as compared to the options of maintaining the status quo opting industry self-regulation, the latter which had the least returns (BCR =

for every shilli
(BCR = 1)
0.259).

Table 4(a): Benefits of Industry Self-Regulation/Ksh

	BENEFIT STREAM		
Year	Costs saved of government administration, licenses, approvals, certificates and permits	Total Benefits	Discounted Benefits (Rate = 14.5%)
0	925,000,000	925,000,000	925,000,000
1	925,000,000	925,000,000	807,860,262
2	925,000,000	925,000,000	705,554,814
3	925,000,000	925,000,000	616,205,078
4	925,000,000	925,000,000	538,170,374
5	925,000,000	925,000,000	470,017,793
6	925,000,000	925,000,000	410,495,890
7	925,000,000	925,000,000	358,511,694
8	925,000,000	925,000,000	313,110,650
9	925,000,000	925,000,000	273,459,083
Total	**9,250,000,000**	**9,250,000,000**	**PVB = 5,418,385,637**

Table 4(a): Costs of Industry Self-Regulation/Ksh

	Costs of ...assification	Boards allowances	Stationary	Utilities	Office maintenance & renovations	Office equipments	Total costs	Discounted Costs (Rate = 14.5%)

0	3,501,750,000	52,215,000	4,646,000	828,000	9,524,760	2,401,200	3,571,364,960	**3,571,364,960**
1	3,501,750,000	52,215,000	4,646,000	828,000	9,524,760	0	3,571,364,960	**3,116,998,917**
2	3,501,750,000	52,215,000	4,646,000	828,000	9,524,760	0	3,571,364,960	**2,722,269,797**
3	3,501,750,000	52,215,000	4,646,000	828,000	9,524,760	0	3,571,364,960	**2,377,528,207**
4	3,501,750,000	52,215,000	4,646,000	828,000	9,524,760	0	3,571,364,960	**2,076,443,849**
5	3,501,750,000	52,215,000	4,646,000	828,000	9,524,760	0	3,571,364,960	**1,813,488,077**
6	3,501,750,000	52,215,000	4,646,000	828,000	9,524,760	0	3,571,364,960	**1,583,832,382**
7	3,501,750,000	52,215,000	4,646,000	828,000	9,524,760	0	3,571,364,960	**1,383,259,722**
8	3,501,750,000	52,215,000	4,646,000	828,000	9,524,760	0	3,571,364,960	**1,208,087,094**
9	3,501,750,000	52,215,000	4,646,000	828,000	9,524,760	0	3,571,364,960	**1,055,097,898**
Total	**35,017,500,000**	**522,150,000**	**46,460,000**	**8,280,000**	**95,247,600**	**2,401,200**	**35,713,649,600**	**PVC= 20,908,370,902**