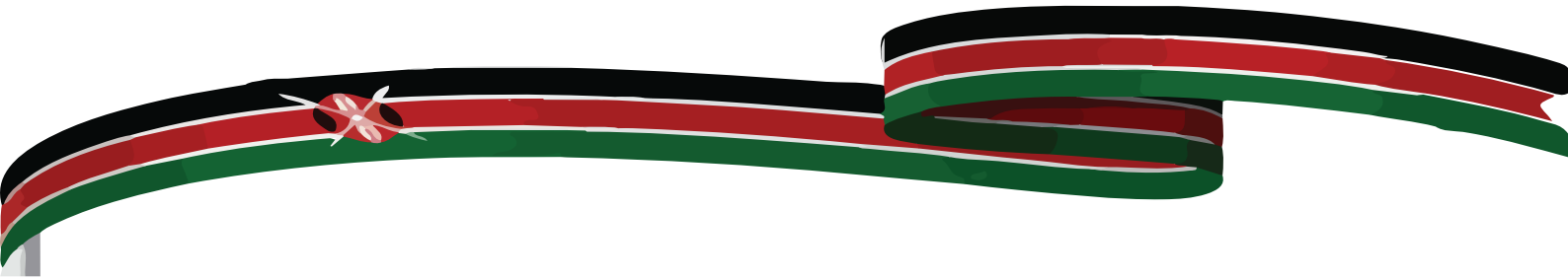
Republic of Kenya

MINISTRY OF AGRICULTURE, LIVESTOCK, FISHERIES AND IRRIGATION

DIRECTORATE OF VETERINARY SERVICES

GUIDELINES FOR THE PRUDENT USE OF ANTIMICROBIALS IN ANIMALS



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Guidelines for the prudent use of antimicrobials in animals

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FOREWORD

Antibiotics are necessary for the treatment and prevention of infectious diseases in farm animals intended for food production and to protect public health from food-borne diseases. The rationale for their use is to protect animal welfare, prevent epidemic spread of infectious animal diseases, to provide high efficiency of animal production, to prevent the transfer of zoonoses from animals to the human population, to warrant safety of food of animal origin and to prevent food-borne diseases. However, it is imperative to note that all antimicrobials used in veterinary practice are the same or closely related to antimicrobials used in human medicine or may induce cross-resistance.

In order to reduce the use of antimicrobials and thus to minimize the development of antimicrobial resistance in veterinary practice, guidelines for prudent use of antimicrobials in animals are recommended.

These guidelines provide practical guidance for national and county governments on the development and implementation of strategies to promote the prudent use of antimicrobials, especially antibiotics, in veterinary services. This should be pursued in accordance with international standards (OIE and CODEX), the Veterinary Policy, the Veterinary Surgeons and Veterinary Paraprofessionals Act Rules and Regulations regarding the Practice of Veterinary Medicines, the Veterinary Medicines Directorate Regulations and Code of Ethics for veterinary surgeons and veterinary paraprofessionals. These measures are expected to contribute to and complement the control of AMR in humans. Apart from the national and county veterinary services, these guidelines address antimicrobial use by other actors in the animal resource industry including producers, wholesalers and retailers of Veterinary Medicinal Products and training institutions.

Successful implementation of these guidelines will require commitment of all stakeholders towards realization of prevention and containment of antimicrobial resistance.

This 25th Day, Oct. 2018

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Dr. Obadia N Njagi, PhD
Director of Veterinary Services

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GLOSSARY

AHSP	**Animal Health Service Professional**
AM	**Antimicrobial**
AMR	**Antimicrobial Resistance**
AMU	**Antimicrobial use**
CAC	**Codex Alimenterius Commission**
CDVS	**County Director of Veterinary Services**
CVL	**Central Veterinary Laboratories**
DVS	**Director of Veterinary Services**
FAO	**Food and Agriculture Organization**
IPC	**Infection Prevention and Control**
KVA	**Kenya Veterinary Association**
MRSA	**Methicillin Resistant Staphylococcus aureas**
MRSP	**Methicillin Resistant Staphylococcus pseudintermedius**
NVAUR	**National Veterinary Antimicrobial Use Register**
OIE	**World Organization for Animal Health**
POM-V	**Prescription only Medicines –Veterinary**
RVIL	**Regional Veterinary Investigation Laboratory**
SPC	**Summary of Products characteristics**
SPS	**Sanitary and Phytosanitary**
VCIA	**Veterinary Critically Important Antimicrobial**
VMD	**Veterinary Medicines Directorate**
VMP	**Veterinary Medicinal Products**
VP	**Veterinary Policy**
VS	**Veterinary Surgeon**
WHO	**World Health Organization**
WTO	**World Trade Organization**

DEFINITIONS

Animal Health Service Professional

Means a person who is authorised by the competent authority and veterinary statutory body to carry out veterinary services

Competent Authority:

Means the Veterinary authority or other Governmental Authority having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures in antimicrobial use

Veterinary Services

Refers to the government and non-governmental organizations that implement animal health, welfare measures and other standards

Veterinarian

Means a person (veterinary surgeon and veterinary paraprofessional) registered or licensed by the relevant veterinary statutory body of a country

to practice veterinary medicine/science in that country(Means

CHAPTER ONE

INTRODUCTION

Background

1. Antimicrobials are used in food animals such as cattle, sheep, poultry, fish and others to prevent or treat infections, safeguard animal welfare and to promote growth. These antimicrobials are often given to animals orally or through injection and can potentially accumulate in the edible tissues or other animal products such as milk or eggs. They may also find their way into soil and vegetables fertilized with manure from treated animals. Antimicrobials are also sometimes used in the farming of seafood as well as used in bee colonies, where drug residues can accumulate in the honey.

2. Diverse classes of antibiotics are used for this purpose, including beta-lactams, tetracyclines, sulfonamides, macrolides, amphenicols, fluoroquinolones, and aminoglycosides, among others. Antimicrobial testing is essential for monitoring and controlling levels of antibiotic residues in foods, which may present potential health risks due to allergic reactions, reproductive problems and carcinogenicity.

3. The extensive use of antimicrobials in human and veterinary services in recent years has accelerated the emergence and spread of resistant microorganisms. This situation has been worsened by the lack of investment in developing new effective antibiotics.

4. Kenya uses antimicrobials in its livestock resource base comprising of 18 million cattle; 17 million sheep; 28 million goats; 3 million camels; 2 million donkeys, 0.3 million pigs and 32 million poultry (Kenya National Bureau of Statistics (KNBS) 2014). Antimicrobials are equally important in farmed and free wildlife.

5. Livestock accounts for nearly 90% of the employment opportunities and about 95% of family incomes in the Arid and Semi-Arid Lands. The sub-sector contributes about 5 % of the Gross Domestic Product (GDP). Globally, 20% of animal production losses are caused by diseases yet 70% additional animal proteins will be required to feed the world by 2050 (Bbosa et al. 2014).

6. It is crucial to preserve antimicrobial efficacy to ensure that animal production keeps pace with growing global demand for quality protein. Controlling emergence of Antimicrobial resistance (AMR) is therefore a priority for the Directorate of Veterinary Services (DVS).

7. Humans and animals, to a large extent, share the same bacteria, 60% of dangerous human pathogens are of animal origin. Many of the same antimicrobials are used to control bacterial infections in both humans and animals.

8. A Study conducted in 2008 by the Kenya Veterinary Association (KVA) on the distribution, use and regulation of veterinary medicines and poisons in Kenya found that antimicrobials were sold in all veterinary drug outlets regardless of whether they were operated by professionals or quacks. It also established the need to separate the regulation of veterinary and human medicines and develop guidelines on the use of antimicrobials in the country.

9. The global burden of AMR is estimated at 700,000 human deaths annually. This figure is projected to reach 10 million by the year 2050 if current trends in Antimicrobial Use (AMU) persist (O'Neill 2014). There is an urgent need to establish estimates for Kenya. AMR is being addressed internationally in order to minimize its development and consequences.

10. The DVS supports and actively collaborates with international organizations such as the World Organization for Animal Health (OIE), the World Health Organization (WHO), the United Nations Food and Ag-

riculture Organization (FAO) and the Codex Alimentarius Commission (CAC) in order to ensure the development and implementation of global strategies and measures designed to restrict the spread of AMR.

11. A national action plan, which is based on a holistic approach, in line with the 'One Health' perspective, has been developed. It involves participation from all sectors and covers all aspects of antimicrobials.

12. The main objectives of the plan are to strengthen the prevention and control of AMR across the human, veterinary and food sectors and to secure the availability and prolong the effectiveness of antimicrobial agents. The action plan emphasizes the importance of international cooperation in tackling AMR, given the global nature of the problem.

13. These guidelines address principles of prudent use of antimicrobials and are without prejudice to provisions contained in national and county laws. They constitute a significant part of the country's overall strategy on AMR. There are a number of provisions relating to the use of antimicrobials and tackling the development of AMR set out in national legislation and therefore binding across the country.

CHAPTER TWO

SCOPE AND PURPOSE

1. Prudent use of antimicrobials in animals can reduce the development of AMR; hence these guidelines focus on antimicrobial use in all animals, particularly the food-producing animals. Antimicrobial resistance is also an ecological problem and its management may require addressing the persistence of resistant microorganisms in the environment.

2. Antimicrobial agents have been defined by the CAC in its Guidelines for risk analysis of food borne antimicrobial resistance and in the Terrestrial animal health code published by the OIE.

3. In these guidelines, the term 'antimicrobial' has been used generically to encompass antibiotics and antibacterial agents, antivirals, anti-fungals and anti-parasitics. However, the use of additional substances in limiting the growth of microorganisms for purposes other than veterinary medicine, such as for plant health, has been excluded from the scope of these guidelines.

4. The purpose of these guidelines is to provide practical guidance for national and county governments on the development and implementation of strategies to promote the prudent use of antimicrobials, especially antibiotics, in veterinary services. This should be pursued in accordance with the Veterinary Surgeons and Veterinary Paraprofessionals Act Rules and Regulations regarding the Practice of Veterinary Medicines, the Veterinary Medicines Directorate Regulations, Code of Ethics for veterinary surgeons and veterinary paraprofessionals and the Veterinary Policy. These measures are expected to contribute to and complement the control of AMR in humans.

5. Apart from the national and county veterinary services, the guidelines address antimicrobial use by other actors in the animal resource industry including producers, wholesalers and retailers of Veterinary Medicinal Products and training institutions.

Regulatory framework

6. The use of antimicrobials in animals must conform to relevant national and county legislation including the Animal Diseases Act; Veterinary Surgeons and Veterinary Paraprofessionals Act, Veterinary Medicines Directorate Regulations and the Veterinary Policy. In particular, antimicrobials must be used as specified in the authorized product information or Summary of Product Characteristics (SPC), package leaflet and labelling.

7. The SPC lists the approved indications for use of a veterinary medicinal product as developed during the risk assessment process. In accordance with VMD Regulations, any application for a marketing authoriza-

tion must be accompanied by the SPC proposed by the applicant and assessed and, if necessary, amended by the competent authority.

8. For veterinary medicinal products that have been on the market for many years, new knowledge may emerge requiring amendments to be made in regard to the terms of marketing authorization. This may involve changes of the recommended dosages in order to improve therapeutic efficacy. Specifically, knowledge of the patterns of resistance and use of antimicrobials may change over time.

9. There is need to develop legislation that allows product information (SPC, leaflet, labelling) on authorized products to be updated by means of referral procedures. The decision to initiate a referral may be based on the risk to human or animal health. Usually, the majority of referral procedures will relate to antimicrobials.

10. SPC harmonization may be necessary when a product is authorized for use in different countries with different conditions. The differences may relate to indications, dosage, dosing intervals and other fundamental aspects determining a medicine's effective and safe use.

11. Many producers are increasingly using medicated feeds as disease prevention measures but there is no legislation to guide this process. Legislation on medicated feeds needs to take into account the conditions for manufacture i.e. mixing of veterinary medicines into feed, placing on the market and use of medicated feed.

Principles for the prudent use of antimicrobials in veterinary practice in Kenya

12. Antimicrobials are essential for the medical care and health of animals and livestock populations. Any use of antimicrobials in veterinary medicine can result in the development of antimicrobial resistance (AMR). The risk increases if such antimicrobials are used inappropriately, for example, in an untargeted manner (e.g. mass medication or use on non-susceptible microorganisms) and under-dosing.

13. The handling of antimicrobials shall be guided by requirements detailed in The Veterinary Surgeons and Veterinary Paraprofessional Act 2011, (The Veterinary Medicine Directorate), Regulations, 2015 in collaboration with Director of Veterinary Services (DVS). General principles on the prudent use of antimicrobials need to be applied as a matter of routine on farms and in veterinary practices.

Issues to be considered before using antimicrobials

14. Prudent use of antimicrobials should lead to more rational and targeted use, thereby maximizing the therapeutic effect and minimizing the development of AMR.

15. Before using antimicrobials, it is prudent to take into account cross- and co-resistance, which means that any exposure to antimicrobials increases the occurrence of AMR. The final outcome of prudent use should be an overall reduction in the use of antimicrobials, predominantly by limiting their use only to situations where they are necessary. In these situations, antimicrobials should be used as targeted treatment and according to best practices, i.e. based on clinical diagnosis and, whenever possible, on the results of microbiological susceptibility tests, and using an antimicrobial agent of as narrow-spectrum as possible.

16. The ultimate objective is to reduce the need for antimicrobials by preventing disease. Animal diseases and infections should primarily be prevented by ensuring biosecurity, following good production and good management practices, and implementing integrated disease control programmes to minimize the occurrence of diseases and eradicate endemic diseases.

17. In cases where it is necessary to use antimicrobials to safeguard animal health and welfare, the following principles should be followed:

18. the prescription and dispensation of antimicrobials must be justified by a veterinary diagnosis in accordance with the current status of scientific knowledge;

19. where it is necessary to prescribe an antimicrobial, the prescription should be based on a diagnosis made following clinical examination of the animal by the prescribing veterinarian;

20. where possible, antimicrobial susceptibility testing should be carried out to determine the choice of antimicrobial;

21. antimicrobial metaphylaxis (the timely mass medication of a group of animals to eliminate or minimize an expected outbreak of disease) should never be used in place of good management practices;

22. routine prophylaxis must be avoided, prophylaxis should be reserved for exceptional case-specific indications;

23. administering medication to an entire herd or flock should be avoided whenever possible;

24. sick animals should be isolated and treated individually;

25. all information relating to the animals, the cause and the nature of the infection and the range of available antimicrobial products must be taken into account when making a decision regarding antimicrobial treatment;

26. a narrow-spectrum antimicrobial should always be the first choice unless prior susceptibility testing, where appropriate supported by relevant epidemiological data, shows that this would be ineffective;

27. the use of broad-spectrum antimicrobials and antimicrobial combinations should be avoided with the exception of combinations contained in authorized veterinary medicinal products;

28. if an animal or group of animals suffer from recurrent infection(s) requiring antimicrobial treatment, efforts should be made to eradicate the strains of the microorganisms by determining why the disease is recurring, and altering the production conditions, animal husbandry and or management;

29. use of antimicrobial agents prone to propagate transmissible resistance should be minimized;

30. the off-label use of antimicrobials for non-food-producing animals (e.g. pets and animals used for sports) should be avoided and strictly limited to very exceptional cases, e.g. where there are ethical reasons for doing so, and only when laboratory antimicrobial susceptibility tests have confirmed that no other antimicrobial would be effective;

- Antimicrobial treatment must be administered to animals according to the instructions given in the veterinarians prescription;

- The need for antimicrobial therapy should be reassessed on a regular basis to avoid unnecessary medication;

- The perioperative use of antimicrobials should be minimized by using aseptic techniques;

- When possible, alternative strategies for controlling disease that have been proven to be equally efficient and safe (e.G. Vaccines) should be preferred over antimicrobial treatment;

- The pharmacovigilance system should be used to obtain information and feedback on therapeutic failures, so as to identify potential resistance issues in the case of use of existing, new or alternative treatment options;

- A network of laboratories with the capacity for performing antimicrobial susceptibility tests in zoonotic and commensal microorganisms and target pathogens should be established to ensure the availability of susceptibility testing (description of their distribution in kenya, both nationally and countywide etc.);

- Particular issues to be considered before using critically important antimicrobials include: many of the antimicrobials used in animals are also used in humans; some of these antimicrobials are critical for preventing or treating life-threatening infections in humans; special consideration is necessary to ensure the

continued efficacy of such antimicrobials and to minimize the development of resistance;

- These antimicrobials should only be used in situations where a veterinarian has assessed, on the basis of antimicrobial susceptibility testing and relevant epidemiological data, that there is no non-critically important effective antimicrobial available;
- In exceptional cases where the use of these antimicrobials under off-label use is unavoidable and legally permissible, prescription and final use should be sufficiently justified and recorded. Such use should be based on clinical grounds, i.E. The prescribing veterinarian considers the use of a particular critically important antimicrobial necessary in order to avoid the suffering of diseased animals, and should also take into consideration ethical and public health concerns ;
- Use of critically important antimicrobials should be limited to cases where no other alternative is available.

CHAPTER THREE

ROLES AND RESPONSIBILITIES IN PRUDENT USE OF ANTIMICROBIALS

31. The primary responsibility for the prudent use of antimicrobials lies with the prescriber, animal owner and the person administering the antimicrobials.

32. Prudent use of antimicrobials requires cooperation between veterinary professionals and public health, veterinary and environmental authorities, industry players, farmers and other parties.

Prescriber

33. The prescriber of the antimicrobial should be a veterinary surgeon familiar with the history of the herd, flock or animal being treated.

34. The prescriber is obliged to make treatment decisions in an independent way and to avoid conflict of interest. The position or status of the prescriber in relation to the farmer should therefore be such as to ensure independent decisions, primarily based on expert knowledge. This can be by:

    - Veterinarians prescribing antimicrobials as guided by the code of ethics;
    - Establishing contracts between the farmers and veterinarians for specific herds to enable development of the understanding of the animals thereby reducing the prevalence of disease and use of antimicrobials.

35. Where it is necessary to prescribe an antimicrobial, the prescribing veterinarian should ascertain by means of an on-site clinical examination or otherwise that the symptoms indicate a bacterial infection.

36. The prescriber should take appropriate samples, whenever possible, from which he/she can identify the pathogen and measure its antimicrobial susceptibility. In acute cases, when treatment needs to be started immediately to avoid animal suffering or to limit the spread of infection, it is still advisable to collect samples.

37. If samples are collected immediately prior to the start of treatment, susceptibility testing can be carried out whilst treatment is being given. The results of this can then be used to validate the choice of antimicrobial and to inform epidemiological follow-up.

38. Where treatment is being given on an on-going basis, repeated culture and sensitivity testing allows

antimicrobial sensitivity trends to be monitored, and the treatment revised subsequently if necessary.

39. The prescriber should follow national and international recommendations for prescribing and administering antimicrobials. Particular attention should be given to:
    - Up-to-date treatment guidelines provided by national authorities including vmd, dvs and kvb to assist veterinarians in selecting the appropriate antimicrobial and fixing a suitable dosing regimen and route of administration;
    - Withdrawal periods to eliminate violative residues in food producing animals;
    - Practice-based protocols for common infections, which take into account regional and local trends in antimicrobial sensitivity, for veterinarians to make optimum prescribing decisions in the absence of sensitivity data.
40. The prescriber should ensure that the most appropriate antimicrobial is selected, based on the most accurate and up-to date information on pharmacodynamics and pharmacokinetics and on accurate and up-to-date information on the functioning of the different classes of antimicrobials.
41. The prescriber should always consider using a single antimicrobial instead of combinations of antimicrobials and should ensure that, where a combination of antimicrobials is prescribed, all the substances in the combination are active against the target pathogen(s).
42. The prescriber is responsible for providing correct information to the person administering the antimicrobial. This should be based, in the first instance, on the information from the product information (package insert) relating to the dose, the indications, the withdrawal periods and prudent use warnings.
43. Veterinary surgeons should report the lack or reduced efficacy of an antimicrobial product to the regulatory and competent authorities without delay.
44. Reporting should be carried out within the existing pharmacovigilance system.
45. Due to the risk of AMR development, the prescriber should give due consideration to alternative interventions, which could prevent recurrence of the disease.

Administrator of the antimicrobials

46. The person administrating antimicrobials to animals is usually the veterinarian, owner of the animal or staff in the home and on farms. These are the people responsible for closely following the prescriber's instructions on administering antimicrobials and alternatives. They play a critical role in observing and monitoring sick animals and animals that do not need antimicrobials.
47. Any person administering antimicrobials should always follow the prescriber's instructions, the product information (package insert) on the product and any available government guidelines or guidelines from other organisations on administering antimicrobials prudently, especially when treating animals with oral medication.

48. In particular, when administering antimicrobials to a group of animals, any other person administering antimicrobials, should ensure that the correct group of animals is treated, at the required dosage, and for the specified duration of the treatment.
49. Where the antimicrobial is administered through feed, the persons administering antimicrobials should monitor whether all animals ingest the adequate/full quantity of the medicated feed containing the therapeutic dose to avoid under-dosing. Where this occurs, the prescribing veterinarian should be informed and should assess the need to modify the treatment regime e.g. by switching to parenteral treatment.
50. In accordance with relevant national legislation, those who administer antimicrobials:

- must obtain the antimicrobials, based on a veterinary prescription, from authorised sources;
- Must ensure the safety of the food production chain, by respecting instructions given by the veterinarian on administering antimicrobials, and ensuring that withdrawal periods are observed, so as to avoid residues of antimicrobials appearing in meat, milk or other products;
- Cooperate with the veterinarian who regularly visits the animals and knows the history and current health status of the herd, flock or animal, to allow him/her to put in place disease prevention measures that also take account of animal welfare;
- Ensure that the correct dose, treatment duration and dosing schedule is followed;
- Be aware of the general aspects of prudent use of antimicrobials and amr, including the need to take samples and perform antimicrobial susceptibility testing on target pathogens;
- Should keep records of all the treatments undertaken on all the animals.

Responsibilities of Animal owners

51. Animal owners perform important roles in ensuring responsible use of veterinary antimicrobials. They are responsible for preventing disease outbreaks and implementing animal health and welfare programmes on their farms. They may, as appropriate, call on the assistance of veterinary surgeons or other suitably trained person who are authorized in accordance with national legislation.
52. Animal owners shall have the following responsibilities(Alimentarius 2005), to:

- Implement animal health plans and preventive measures in cooperation with the veterinary authority (e.G. Vaccination programmes, disease control strategies, mastitis control plan);
- Use veterinary antimicrobials in the species, for the uses and at the doses on the approved labels and in accordance with the prescription, product label instructions or the advice of a veterinary professional familiar with the animals and the production site;
- Isolate sick animals and dispose of dead or dying animals promptly under conditions approved by the veterinary authority;
- Comply with storage conditions of veterinary antimicrobials according to approved product labelling;
- Ensure hygienic conditions regarding contact between animal handlers including producers, veterinary professionals and the sick animals;
- Comply with recommended withdrawal periods to ensure that residue levels in animal derived food do not pose a risk to consumers;

- Avoid use of expired veterinary antimicrobials and to dispose of all unused veterinary antimicrobials in accordance with the provisions on the product label;
- Ensure sound management of animal wastes and other materials to avoid dissemination of antimicrobial agents and resistance determinants into the environment;
- Avoid using veterinary antimicrobials as a replacement for good management and hygiene, or other disease prevention methods such as vaccination;
- Regularly provide information to veterinary professionals on recurrent disease problems;
- Maintain all clinical and laboratory records of microbiological and susceptibility tests as advised by the veterinary authorities. These data should be shared with the veterinary professional responsible for treatment of the animals in order to optimize the use of veterinary antimicrobials.
- Prevent unnecessary contact with and transmission of resistant bacteria to personnel, including farm workers;
- Assist veterinary authorities in surveillance programs related to antimicrobial resistance;
- Keep records of all veterinary antimicrobials used, including:
    a. Name of the veterinary antimicrobial or active substance and batch number;
    b. Name of supplier;
    c. Date of administration;
    d. Identification of the animal or group of animals to which the veterinary antimicrobial was administered;
    e. Clinical conditions treated;
    f. Quantity and duration of the antimicrobial agent administered;
    g. Withdrawal periods;
    h. Results of laboratory tests;
    i. Results of treatments;
    j. Name of the prescribing veterinary surgeon or other suitably trained person authorized in accordance with national legislation.

Veterinary Pharmaceutical industry, wholesalers and retailers

53. A veterinary prescription is required for dispensing some veterinary medicinal products as specified in the national legislation. Veterinary Prescription Only Medicines (VPOM) shall not be advertised to the general public.
54. Stakeholders who supply antimicrobials to the end-user, such as retail veterinary pharmacies, are responsible for ensuring that a valid prescription is presented at the time antimicrobials are supplied, including in the case of internet sales, and for providing clear and correct information on product use.
55. The pharmaceutical industry and wholesalers should base their advertising on the VMD regulations on advertisement to provide objective information in line with the package insert. The information provided should also highlight the risk of AMR and the need for prudent use.

56. The variation of pack size and the strength of the available antimicrobial formulations should be avoided aftermarket authorization. Veterinary antimicrobials shall be sold in the original sealed and labelled package as registered by the VMD.
57. The pharmaceutical industry, wholesalers and those involved in the sale of antimicrobials should cooperate to implement a pharmacovigilance programme and measures to monitor and control the supply and use of antimicrobials, such as providing information on veterinary sales and the results from industry monitoring programmes to competent authorities.
58. The pharmaceutical industry should be encouraged to develop and market alternatives to antimicrobials, such as vaccines and rapid and affordable diagnostic tests.
59. The pharmaceutical industry should also prioritise tasks like dose optimisation, based on relevant pharmacokinetic and pharmacodynamic data, modern formulations of old classes of antibiotics such as penicillins, which are still effective against many animal diseases, and orphaned antimicrobials.
60. The development of fixed combinations of veterinary antimicrobials should be avoided unless adequately justified.

Animal feed manufacturers

61. Animal feed manufacturers must comply with the legal requirements for feed hygiene, implement best practices in the production of safe and nutritionally balanced feed, and ensure adequate feed formulation. They should ensure that all ingredients meet the required standards and that the manufacturing process does not allow the feed to be contaminated with harmful agents, which could compromise the safety of the feed.
62. Medicated feed may only be produced by a feed manufacturer on a veterinarian's prescription. The manufacturer must be approved for the manufacture of medicated feed by the relevant regulatory agency.
63. The manufacturer must follow good manufacturing practices and ensure appropriate mixing to guarantee the homogeneity of antimicrobials in the feed. He must take steps to avoid cross-contamination and minimise the transfer of antimicrobials to subsequent batches of feed.
64. The medicated feed must be appropriately labelled and only be supplied to the end-user with the prescription. Detailed records should be kept of the antimicrobials used, the medicated feed produced and the destination.

Food business operators

65. Food business operators, including retailers, should maintain Supplier Quality Assurance systems to guarantee that their suppliers source from producers who apply the principles of prudent antimicrobial

use. Consumer organisations should proactively support such initiatives.

Veterinary faculties and other training institutions

66. Veterinary faculties and other training institutions should ensure that sufficient emphasis is given to the prudent use of antimicrobials and the problem of AMR in their training programmes, and that knowledge relating to these areas is kept up to date.
67. The programmes should focus on developing learning materials and techniques relating to ways to improve and promote breeding and husbandry practices that promote animal health. Such practices may include bio-security measures; good farming practices and herd health planning that prevent infections and therefore reduce the need for antimicrobials.
68. Sensitization of primary school pupils and secondary school students on prudent use of antimicrobials in animals should be undertaken.
69. Universities and other research facilities should give priority to research in the area of AMR.
70. In veterinary medicine, research focus should be given to:
    - Developing alternative, preferably preventive, tools for infection control;
    - Evaluating the impact of the use of antimicrobials in animals on public health and the environment;
    - Further investigating pharmacokinetic and pharmacodynamic data and using models to simulate the effects of different dosing schedules (based on different combinations of: disease, pathogen, target tissue and animal species). The results from modelling should provide a scientific background for setting effective dosing schedules in practice;
    - Further investigating co-resistance and cross-resistance, including the co-resistance of disinfectants and antimicrobials and the co-resistance and development of resistance of antimicrobials to certain metals;
    - Developing new classes of antimicrobials.
71. Veterinary faculties should provide information on the risk of nosocomial infections in veterinary practices and clinics, on the use of monitoring procedures to detect and report occurrence of infections and on the use of infection prevention and control measures to minimise occurrence.
72. Scientific publications should promote the principles of prudent use.

Veterinary professional associations and statutory bodies

73. Veterinary professional associations should promote prudent use of antimicrobials. Veterinary professional associations and statutory bodies should provide specific training for veterinary practitioners on the prudent use of antimicrobials and AMR through Continuous Professional Development programs. They should include principles on the prudent use of antimicrobials in their codes of conduct for veterinarians.

Industry stakeholder associations

74. Industry stakeholder associations should support the development and implementation of initiatives to promote the prudent use of antimicrobials and tackle AMR. They should develop appropriate communication materials and provide adequate information about the prudent use and risk of AMR to their members. They should also support national initiatives involving the collection of data on sales and distribution of antimicrobials.
75. Industry stakeholder associations should promote quality schemes and systems of production and supply that implement the principles of prudent use.

Farmer Associations

76. Farmer associations in collaboration with veterinary professionals should promote the principles of prudent use of antimicrobials among their members. They should inform their members of the implications of the use of antimicrobials in animals for the risk of AMR, and thus help to minimise the use. Other aspects such as the risk of AMR due to direct contact with animals should also be publicised.
77. To reduce the need for antimicrobial use, farmer training courses and guidance materials should include information on preventive measures that promote animal health; in particular good husbandry practices, implementation of biosecurity measures, good farming practices and herd health planning. Training should also cover the administration of antimicrobials and environmental risks.

Competent Authority

78. The competent authority on AMU is the Director of Veterinary Services (DVS) who should proactively develop appropriate risk-based measures to ensure the prudent use of antimicrobials, verifying and enforcing their application, and evaluating the results. The DVS should provide sufficient resources for implementing these measures and for research and awareness campaigns. In particular, DVS should:
    - Ensure that national strategies are developed and implemented. Such strategies should be based on co-operation between the veterinary services, the human health authorities and other relevant authorities (e.G. Environmental authorities);
    - Monitor the implementation of the national strategy, in order to evaluate and assess the impact and effectiveness of measures taken under it;
    - Carry out in collaboration with other regulatory agencies, where appropriate, targeted checks on veterinarians with questionable patterns of prescription. Farm inspections may also be carried out in order to evaluate animal husbandry and animal health conditions;
    - Consider the introduction of mandatory herd health programmes promoting best practices, and ensure that hygiene standards are improved on farms where problems have been identified;
    - Support and promote research into alternatives to antimicrobials, diagnostic tests and the prudent use of antimicrobials;
    - Fund and support the development and dissemination of guidelines for both the prudent use of antimicrobials and hygiene measures; fund and support awareness and training campaigns on amr and the

prudent use of antimicrobials aimed at veterinarians and farmers;

- Develop control measures to limit the spread of resistant bacteria when a type of amr is low or emerging. This may include increased biosecurity measures, identification of carriers, animal quarantine, restrictions on the movement of people and investigations.
- Set up amr surveillance and supplementary programmes; residue monitoring programmes and monitor their enforcement.

Laboratories

79. The National network of laboratories for diagnosis, drug residue analysis, quality assurance and AMR monitoring comprises of the Central Veterinary Laboratories (CVL) and six Regional Veterinary Investigation Laboratories (RVILs); private laboratories; universities and research institutions.
80. The CVL will provide scientific advice and assistance to the RVILs, organise annual proficiency tests for susceptibility testing for the RVILs and harmonise the implementation of antimicrobial susceptibility testing methods. CVL will provide scientific and technical reports to the competent authorities in the diagnosis, drug residue analysis, quality assurance and monitoring AMR.
81. Designated universities and research institution laboratories will provide research, residue monitoring, quality assurance and diagnostic services and submit scientific and technical reports to the competent authority.
82. Designated private laboratories will provide diagnostic services and submit scientific and technical reports to the competent authority.
83. The laboratories performing antimicrobial susceptibility tests and providing results on target pathogens are essential in order to guarantee that susceptibility testing is available to practitioners in the country. Laboratories should provide the practitioner with the results of testing and any other relevant information which may be useful e.g. resistance to narrow-spectrum antimicrobials. Results should be based on standardised methodologies and clear interpretative criteria.
84. Laboratories should take part in external proficiency tests for antimicrobial susceptibility testing and other relevant microbiological tests, in order to ensure that their results are valid.

Oral Administration of Antimicrobials to Groups of Animals via Feed and Drinking Water

85. Oral antimicrobial treatment is often administered to groups of animals through medicated feed or by adding the antimicrobial to drinking water or feed on the farm. Whenever possible, individual treatment of the affected animal(s) (e.g. administration through injection) should be preferred to group or mass treatment. When using group treatment, the following points should be taken into account:
    - Oral antimicrobial treatment given via medicated feed or drinking water must only be administered where prescribed by a veterinarian;

- Antimicrobials should only be administered to groups of animals via feed or drinking water where there is evidence of microbial disease or infection. Such treatment should not be given as a prophylaxis;
- The administration of antimicrobials via feed or water should be limited to the animals requiring treatment, and the drug delivery systems should be appropriate for the intended treatment;
- The quantities of antimicrobials administered in feed or water should be monitored and documented on a continuous basis, especially in intensive food-animal production systems;
- The instruction given in the product information (spc, leaflet, label) and by the veterinarian must be complied with, both in terms of dosage and duration of treatment;
- Where an antimicrobial is administered through feed, it is important to ensure the homogeneity of distribution of the drug, in order that each animal obtains the required therapeutic dose for treating the disease in accordance with the prescription;
- Extra/off-label use should be limited to the necessary minimum and to exceptional occasions where no other authorized treatment options are available;
- Adequate, clean storage facilities should be available on the farm to ensure proper storage of the medicated feed; access to these facilities should be restricted.

CHAPTER FOUR

AWARENESS CREATION AND COMMUNICATION

86. It is only possible to minimize the development of AMR through the prudent use of antimicrobials if all parties involved are well informed.
87. All users of antimicrobials should be educated in the proper use of antimicrobials including access, handling, storage, administration, and completion of course of treatment, avoidance of under dosing, observance of withdrawal periods, disposal and record keeping.
88. Education programs should promote best practices, including correct treatment, measures to prevent and reduce the transmission of pathogens, infection control and hygiene measures.
89. Animal Health Service Providers (AHSP) have a responsibility to educate staff, clients, and other animal handlers on the prudent use of antimicrobials, how to optimize the use of antimicrobials, Infection Prevention and Control (IPC) and for ensuring such training occurs.
90. Animal Health Service Providers should continually update their knowledge of methods of disease prevention, new therapeutics, and of other issues such as drug resistance trends, to ensure the prudent use of antimicrobials.
91. Awareness campaigns therefore play an important role, and need to be regularly repeated and updated.
92. Prudent use campaigns in the veterinary sector are targeted at specific groups, including farmers, veterinarians, and veterinary paraprofessionals involved in animal production, animal service provision and pet owners.
93. The campaigns may include a number of approaches, for example, providing sectoral guidelines on good

practice, holding seminars, displaying posters in veterinary practices, pamphlets, print or electronic media, websites, field days, exhibitions and barazas.

94. Relevant networks and stakeholder organizations play an important role in the success of such campaigns and they should also be supported by the competent authority and the regulator.

95. Guidelines should also provide practical tools for implementation and should encourage the parties concerned to be proactive in taking steps to reduce the threat of AMR.

96. Campaigns aimed at pet owners, designed to increase their awareness of the importance of prudent use of antimicrobials and of hygiene are also encouraged.

97. Campaigns may also be targeted at consumers, to encourage them to demand food that is produced in accordance with good veterinary practices, which require the amount of antimicrobial agents used to be kept as low as possible. Positive examples of best practices in animal husbandry can strengthen consumer confidence and increase public demand for food produced with minimal use of antimicrobials.

CHAPTER FIVE

COMPLIANCE AND ENFORCEMENT

98. Veterinary antimicrobials are essential for controlling a great number of diseases in both animals and humans. Hence they should be manufactured, marketed, distributed, prescribed and used responsibly within agreed systems that are regularly and adequately audited.

99. The continued availability of veterinary antimicrobials, which are critical for animal welfare and animal health and consequently human health, will ultimately depend on the responsible use of these products by all those involved in their authorization, production, control, distribution and use in animals.

100. Microbes move freely within the country and around the world, unhindered by borders but human responses to diseases are limited by jurisdictional boundaries. Thus such responses must take into consideration international, national and county laws.

101. To effectively prevent and control infectious diseases, veterinary and paraveterinary professionals and other users of veterinary antimicrobials shall:

- Constantly comply with regulations and national legislations (364 2015, prescott 2008) ;
- Use these guidelines in conjunction with existing antimicrobial guidelines developed by the oie;
- Conduct surveillance of antimicrobial resistance in the course of their work;
- Promptly report incidences and prevalence of antimicrobial resistance and adverse reactions to the director of veterinary services and vmd.

102. Veterinary antimicrobials will be used only when necessary and in an appropriate manner, thus:

- A prescription for veterinary antimicrobials shall precisely indicate the treatment regime, the dose, route of administration, dosage intervals, duration of treatment, withdrawal period and the amount of antimicrobial to be delivered depending on the dosage, the number and the weight of the animals to be treated;
- All veterinary antimicrobials shall be prescribed and used according to the conditions stipulated in the national legislation (vsvp cap 366) and relevant regulations (vmd regulations 2015).

103. All veterinary antimicrobials shall be:

- Prescribed by a veterinary surgeon in accordance with relevant legislation or used under conditions stipulated in the relevant legislation ;
- Supplied only through licensed or authorized distribution systems;
- Administered to animals by a veterinary surgeon or under the supervision of a veterinary surgeon or other suitably trained persons authorized in accordance with national legislation. Proper records will be kept of administration of veterinary antimicrobials.

104. Advertising of veterinary antimicrobials will be conducted in compliance with:

- The marketing authorization granted, particularly the content of the summary of product characteristics and
- The relevant national legislations (vspv act cap 366) and regulations (vmd regulations 2015).

105. The veterinary pharmaceutical industry should respect principles of responsible and prudent use and should comply with established code of ethics on advertising, including to:

- Distribute information in compliance with the provisions of the granted authorization;
- Not advertise veterinary medicinal products (vmp) containing antimicrobial agents directly to the food animal producer.

106. The choice of a veterinary antimicrobial to be used shall be guided by:

- The expected efficacy of the treatment based on:
  a. Clinical experience of the veterinarian,
  b. Spectrum of the antimicrobial activity towards the pathogens involved,
  c. Epidemiological history of the production unit particularly in regard to the antimicrobial resistance profiles of the pathogens involved. Whenever possible, it is preferred that the antimicrobial profiles should be established before the commencement of treatment. Should a first antimicrobial treatment fail or should the disease recur, the use of a second veterinary antimicrobial should be based on the results of microbiological tests,
  d. Appropriate route of administration,
  e. Response to initial treatment
  f. Known pharmacokinetics or tissue distribution to ensure that the selected veterinary antimicrobial is active at the site of infection,
  g. Prognosis.
- The need to minimize the adverse health impact from the development of microbial resistance based on:
  a. The choice of the activity spectrum of the veterinary antimicrobial drug,

b. The targeting of specific microorganism,

c. Known or predictable susceptibilities using antimicrobial susceptibility testing;

d. Optimized dosing regimen,

e. The use of effective combinations of veterinary antimicrobials,

f. The importance of the antimicrobials to veterinary and human medicine and

g. The route of administration.

107. The appropriate use of veterinary antimicrobials is mainly a clinical decision that is based on the experience and expertise of the prescribing veterinarian and the accurate diagnosis, based on adequate diagnostic procedures.

108. There may be occasions when animals, which have been exposed to pathogens, may need to be treated without recourse to an accurate diagnosis and antimicrobial susceptibility testing in order to prevent the development of clinical disease and for reasons of animal welfare.

109. Whenever the labelling of veterinary antimicrobials allows for flexibility, the veterinarian should consider a dosage regimen that is long enough to allow an effective recovery of the animal but short enough to limit the selection of resistance in food borne and/or commensal microorganisms.

Extra/off-label use

110. The extra-label use of a veterinary antimicrobial drug may be permitted in appropriate circumstances and should be in compliance with the national legislation in force including the administrative withdrawal periods to be used. It is the veterinary surgeon's responsibility to define the conditions of responsible use in such a case including the therapeutic regimen, the route of administration and the duration of the treatment. Extra-label use of antimicrobial growth promoters is not to be permitted.

Recording

111. Records on am dispensing and use should be kept at all outlets according to relevant national legislations (cap 366 and vmd regulations 2015) and should be accessible to authorized veterinary professionals. (A template will be developed for records capture at outlets, farm, hatcheries, and vet clinics/hospitals)

112. For investigation of antimicrobial resistance, veterinary professionals should:

- Record the antimicrobial susceptibility testing results;
- Investigate adverse reactions to veterinary antimicrobials including lack of expected efficacy due to antimicrobial resistance, and report it, as appropriate, to the regulatory authorities;
- Farm records on the use of antimicrobials should be mandatory and be periodically reviewed to ensure compliance with the directions on use.

CHAPTER SIX

DISEASE PREVENTION AND REDUCING THE NEED TO USE ANTIMICROBIALS

113. AMR is not only an animal health and economic concern, with implications for decreasing the efficiency of antimicrobial treatment in animals, but is also a public health concern due to the transmission of antimicrobial-resistant bacteria through the food chain and the transmission of resistance from animal bacteria to human bacteria.

114. To be effective in mitigating the risk of amr, and taking into account co-resistance and cross-resistance, the prudent use of antimicrobials needs to bring about an overall reduction in the use of antimicrobials.

115. Preventing infections in the first instance is the best way to achieve this reduction and to minimize the need to use antimicrobials, as reducing the number of infections reduces the number of treatments needed.

116. The approach is supported by the veterinary policy, as it is fully in line with the principle promoted by this policy that prevention is better than cure. A reduction in the incidence of animal disease and zoonotic infections should also minimize the need for, and use of, antimicrobials.

117. The objective of reducing the use of antimicrobials is also in line with animal welfare that aims to prevent overstocking. This is believed to be a major risk factor in the emergence and spread of infections that require the use of antimicrobials to reduce the suffering of sick animals.

118. In general, the following measures can help to prevent diseases and reduce the need to use antimicrobials in all species:

- Application of world trade organisation/ sanitary and phytosanitary (wto/sps) measures;
- Implementing hygiene and biosecurity measures (including measures designed to prevent the introduction of infections), such as: keeping separate protective clothing and boots for each unit; limiting access to farms and units; making hand washing and hand disinfection facilities (with liquid soap, hot and cold water) available close to the workplace; ensuring quick removal of and safe disposal of dead animals; applying the 'all-in all-out' system in each unit and paddocks; following a strict schedule for cleaning and disinfection; and performing regular disinfection controls;
- Producing clear protocols for the prevention of infectious diseases and infection control and hygiene; making these available on farms;
- Improving husbandry systems by providing appropriate housing, ventilation and environmental conditions for animals and appropriate and clean facilities during transport (e.G. The lairage area and vehicles);
- Establishing integrated production systems which avoid the need to buy and mix animal populations and to transport animals with unknown disease status;
- Avoiding stressful situations which can weaken animals' immune systems and make them more susceptible to infections, e.G. Limiting the transport of animals, minimising transport time and ensuring that the recommended animal population density is adhered to;
- Implementing other zootechnical measures to minimise disease and decrease use of antimicrobials;

- Introducing herd-specific health plans designed to achieve a consistent stepwise improvement in herd health and avoiding and discouraging health programmes in which animals are systematically treated with antimicrobials prophylactically;
- Implementing programmes to control specific animal diseases (both viral and bacterial) by means of vaccination;
- Using scientifically proven, effective and safe alternatives to antimicrobials;
- Using only safe, high-quality feed and water;
- Providing incentives to farmers to encourage them to adopt effective preventive measures, to improve animal health and welfare standards and to monitor pathogens and their sensitivity at herd level, with the ultimate objective of ensuring evidence-based use of antimicrobials in individual herds in line with the prudent use principles set in this guideline.
- Breeding for disease resistant animals.

Bovines and small ruminants

119. Mass or group medication of cattle is uncommon in kenya, although calves can be subjected to group treatment using antimicrobials. Treatment given to cows at drying-off is of particular importance. The measures to be taken include:

- Avoiding the prophylactic use of antimicrobials in new-born calves, kids and lambs (e.G. Antimicrobials added to milk replacers) by instead implementing good farming practices (e.G. To ensure high standards of hygiene);
- Avoiding the prophylactic use of antimicrobials and develop preventive strategies (e.G. Vaccinations and feeding colostrum to calves, kids and lambs), especially for the allotment of calves, lambs, kids and beef cattle, sheep and goats;
- Avoiding the systematic treatment of cows at drying-off, and considering and implementing alternative measures on a case-by-case basis;
- Establishing thorough hygiene measures and good farm practice and management strategies to minimise the development and spread of mastitis in dairy cows, ewes and does;
- Promoting the use of rapid diagnostic tests (e.G. Standardized tests with chromogenic media) for identifying mastitis causing pathogens, in order to minimize the use of both intramammary and injectable antimicrobials in milking cows;
- Avoiding feeding calves, lambs and kids with waste milk from cows, ewes and does that have been treated with antimicrobials.

Poultry

120. Action is needed to avoid the prophylactic and often recurrent group medication of poultry, which is frequently carried out on farms, immediately before or after transport of day-old chicks, or in some cases to address losses of productivity.

121. The injection of antimicrobials into eggs or day-old chicks in hatcheries should be avoided entirely, unless justified for exceptional reasons that are clearly described in national or international guidelines.

122. Hatcheries should keep records of any use of antimicrobials in eggs and should provide their records to the competent authority on request. Antimicrobials should not be used routinely on the arrival of day-old

chicks at the farm.

123. The prophylactic use of antimicrobials at this stage can be avoided by ensuring good hatchery hygiene and through good management of day-old chick production e.G. Temperature control, hygiene and stimulation of drinking and eating.

124. Vaccination management should include measures to avoid a stress reaction and improvements to the availability of autogenous vaccines.

125. Specific animal welfare programmes should be introduced, potentially including footbath scores.

126. The use of antimicrobials for non-infectious diseases with limited secondary infections should be avoided. Husbandry, management and breeding policies should be evaluated to avoid the recurrence of such diseases. The use of 3rd, 4th and 5th generation of cephalosporins in poultry including eggs should be avoided due to the risk of amr spreading to humans.

127. Among the veterinary critically important antimicrobials (vcia), some that are also considered of critical importance for human and animal health e.G. Fluoroquinolones (oie) should:

- Not to be used as preventive treatment in feed or water or in absence of clinical signs;
- Not to be used as first line treatment, unless justified with bacteriolgical tests;
- Be extra label/off label limited and reserved for instances no alternatives are available.

128. Antimicrobials shall not be used as a specific method to control salmonellosis in poultry. In order to ensure that kenya's targets for reducing salmonellosis are met, all national control programmes should include biosecurity measures designed to prevent salmonella infection in poultry farms. The introduction of such measures also has a positive effect in terms of preventing other diseases.

Pigs

129. Antimicrobials are most often used in pigs to relieve weaning diarrhoea, intestinal infections associated with collibacillosis and respiratory diseases often associated with transport and the stress caused when pigs originating from different farms are brought together or when animals are housed in holdings with inappropriate ventilation systems, unsuitable feeding methods and/or insufficient biosecurity measures.

130. When an infection requiring the use of antimicrobials is found in certain holdings, an in-depth analysis of the problem should be carried out, and steps taken to limit the spread and prevent the recurrence of the infection. Possible measures to be taken include:

- Avoiding the prophylactic use of antimicrobials in new-born piglets (and after weaning), as a part of a herd health strategy;
- Implementing an 'all-in all-out' system of production, thoroughly cleaning and disinfecting production units when animals move into, within and out of the herd;
- Isolating the pathogen and considering a vaccination strategy where available (e.G. Atrophic rhinitis);

- Checking and ensuring that the ventilation system and general housing environment are functioning correctly and making sure it is possible to change the conditions if there is a high frequency of recurring respiratory diseases or environmental conditions are poor (e.G. In hot seasons, when there can be a dramatic increase in temperatures and in the ammonia concentration in the environment, which, if the ventilation system is not adjusted, dusty conditions exacerbate respiratory conditions);
- Establishing appropriate feeding strategies based on the pigs' age, especially at weaning;
- Avoiding mixing within the herd, or quarantining stock for an appropriate period prior to mixing;
- Reassessing weaning management in cases of recurrent weaning diarrhoea (considering in particular hygiene, the age of the pigs, the use of 'all-in all-out' systems, ways of reducing the stress suffered by the animals and alternatives to the prophylactic use of antimicrobials);
- Eliminating recurrent cases of post-partum dysgalactiae syndrome by ensuring appropriate selection of sows, good hygiene at parturition and adapted feeding;
- Preventing the trading and movement of diseased pigs to mitigate the spread of infections and organisms such as methicillin resistant staphylococcus aureus (mrsa).

131. There is an increasing need to establish integrated pig production systems that avoids the mixing of animals and minimises long-distance transport e.G. Closed farms and an integrated approach between breeding and fattening farms. In addition, breeding targets should focus not only on production parameters but also on the increased resistance to infections. A holistic approach to disease prevention should be adopted.

Camels

132. The same strategies as are used for reducing the use of antimicrobials in other farm animals should apply in camels. The use of vaccines to tackle some of the diseases e.G. Rabies, anthrax, tetanus, hemorrhagic septicaemia, pasteurellosis etc. Most commonly occurring in camels has been demonstrated to be particularly effective. Use of antimicrobials in camels to treat hemorrhagic septicaemia is of particular importance.

133. The measures to be taken include:

- Avoiding the prophylactic use of antimicrobials by instead implementing good husbandry practices (e.G. Adopting routine vaccinations);
- Avoiding the systematic treatment of milking camels, and considering and implementing alternative measures on a case-by-case basis;
- Establishing thorough hygiene measures and good husbandry and management strategies to minimise the development and spread of mastitis in milking camels;
- Promoting the use of rapid diagnostic tests (e.G. Standardised tests with chromogenic media) for identifying mastitis causing pathogens, in order to minimise the use of injectable antimicrobials in milking camels;
- Avoiding feeding calves, with waste milk from camels, that have been treated with antimicrobials.

Aquaculture

134. The same strategies as are used for reducing the use of antimicrobials in other farm animals should also be employed in aquaculture. The use of vaccines to tackle some of the bacterial diseases most commonly occurring in fish has been demonstrated to be particularly effective. The following actions should be implemented to prevent and reduce the need to use antimicrobials in aquaculture:

- Encouraging production systems that provide appropriate environmental conditions for aquaculture animals kept on farms, in particular with regard to water quality, water flow rates, oxygen levels and nutrition;
- Encouraging the use of antimicrobial sensitivity testing prior to treatment, wherever possible;
- Encouraging the development of specific disease surveillance programmes to identify and help prevent possible outbreaks of disease;
- Implementing specific hygiene and biosecurity measures, including measures to prevent the introduction and spread of infections, such as:
- Operating an 'all-in all-out' system per unit or farm,
- Applying single bay management where possible,
- Ensuring proper cleaning and/or disinfection of units and farms between production cycles, and
- Carrying out fallowing of sites between production cycles;
- Keeping separate equipment, protective clothing and boots for each unit or farm and enforcing restrictions on access to the farm;
- Quickly removing dead fish and ensuring systems are in place for handling, disposing of and treating by-products;
- Ensuring a system is in place for collecting blood and/or water when slaughtering on site;
- Developing systems to avoid the spread of diseases by transport (e.G. Treatment of transportation water and avoiding contact with other aquaculture animals during transport);
- Encouraging the development and use of effective vaccines for aquaculture;
- Recommending adequate welfare parameters, e.G. For stocking density.

Rabbits

135. The main indications requiring group medication in rabbits are weaning diarrhoea, coccidiosis, and respiratory problems. Preventive measures include:

- Optimising ventilation (avoidance of cold drafts) and vaccinating against pasteurellosis;
- Avoiding overcrowding and fighting between animals and making sure rabbits do not come into contact with sharp objects;
- Ensuring that dietary changes are made gradually;
- Ensuring thorough cleaning and disinfection of pens;
- Quarantining newly purchased rabbits before introducing them into the main group.

Equines

136. Prudent use of antimicrobials is a critical component of equine medicine. Although the basic principles of equine antimicrobial therapy are no different to those in other animal species, there are some special considerations.

137. As hindgut fermenters, equines are susceptible to adverse gastrointestinal consequences of antimicrobial administration. In addition, the temperament of equines may influence selection of treatment options based on the ability of the veterinarian or owners to safely administer antimicrobials via different routes.

138. The measures to be taken include:

- Avoiding the prophylactic use of antimicrobials in equines that lead to adverse effects including colitis, allergic reactions, immune-mediated disease and arthropathy e.G. Lincomycin, clindamycin. Oral penicillins are considered high risk and should never be used in horses while enrofloxacin is associated with arthropathy in foals;
- Adequate stall rest and a well-ventilated stable and supportive care are the most important components in controlling respiratory infections;
- Establishing thorough hygiene measures and good farm practice and management strategies to minimise the development and spread of respiratory diseases.

Bees

139. Bees also suffer from bacterial infections (foulbrood diseases). The use of antimicrobials to tackle some of the bacterial diseases most commonly occurring in bees has been demonstrated to be particularly effective. The following actions should be implemented to prevent and reduce the need to use antimicrobials in apiculture:

- Encouraging production systems that provide appropriate environmental conditions for apiculture, in particular with regard to water quality, oxygen levels and nutrition;
- Encouraging the development of specific disease surveillance programmes to identify and help prevent possible outbreaks of disease;
- Implementing specific hygiene and biosecurity measures, including measures to prevent the introduction and spread of infections, such as:
    a. Import/export of the queen bee;
    b. Ensuring proper cleaning and/or disinfection of units and farms between production cycles, and
    c. Use of modern beehives.
- Keeping separate equipment, protective clothing and boots for each unit or farm and enforcing restrictions on access to the farm;

Wildlife

140. Wildlife can be subjected to treatment using antimicrobials. Treatment given to crocodiles suffering from coccidiosis, chlamydiosis, mycoplasmosis, and pox is of particular importance. On the other hand, ostriches suffer from common poultry diseases. The measures to be taken include:

establishing thorough biosecurity measures and good farm practice and management strategies to minimise the contact between wildlife and domestic animals;

ensuring routine vaccinations to control infections and avoid use of antimicrobials;

Other species

141. Other species include pets and other non-food-producing species. The following should be considered:

- When clinical infection with MRSA or Methicillin Resistant Staphylococcus pseudintermedius (MRSP) is suspected or detected in companion animals, they should be monitored for MRSA/MRSP with a view to possible quarantine. It is very important that the risk of the infection spreading in animal hospitals and veterinary clinics is minimized. Animals showing clinical signs should therefore be handled separately. In dog kennels or in day care facilities, dogs showing clinical symptoms should not be kept with other animals.

- The off/extra-label use of antimicrobials to treat non-food-producing animals should be avoided, especially when the drugs are of critical importance for human health e.g. carbapenems and tigecycline. Their use should only be considered in very exceptional cases, e.g. when laboratory susceptibility testing has confirmed that no other antimicrobials will be effective and where there are ethical reasons to justify such a course of treatment.

CHAPTER SEVEN

SURVEILLANCE AND MONITORING

142. Harmonized and comparable data on the use of antimicrobials and AMR in the food chain is necessary for carrying out risk assessment, for research purposes, and for evaluating the effectiveness of the measures taken to tackle AMR.

143. Harmonized monitoring and surveillance systems should be used across the country, in order to collect comparable data from AHSP and animal species, and so as to allow comparison with human data.

144. AHSP are expected to timely provide data on the use of antimicrobials in veterinary medicine for the National Veterinary Antimicrobial Use Register (NVAUR) to establish technical units of measurement for reporting the use of antimicrobial agents in animals.

145. AHSP are expected to analyze and share the data on antimicrobial use collected at every level. This should preferably include data on usage by species and age group, and should be compared to AMR monitoring data. AHSP that are able to collect detailed data on the use of antimicrobials by age group are expected to use these data to set benchmarking values for each age group, which could then be used by the country.

146. AHSP must monitor antimicrobial resistance in zoonotic, pathogenic and indicator bacteria taken from food-producing animal populations and their products, through antibiotic sensitivity using standardized testing methods and data sharing practices and share the data.

147. AHSP are encouraged to perform additional sampling for analysis to monitor AMR in other bacteria (e.g. MRSA and animal pathogens), at other points in the food chain and in other food and animal species.

148. Practicing veterinarians or veterinary paraprofessionals shall observe adverse reactions when they occur, and their key role in reporting them will directly contribute to the safety of these medicines.

149. It is important that adverse reactions are reported to the DVS and VMD even if a relation to the product(s) used is only suspected, especially the following types of reaction:

- An adverse reaction, which results in death;
- An adverse reaction, which results in significant, prolonged or permanent signs;
- An unexpected adverse reaction, which is not mentioned on the label or package insert;
- An adverse reaction to veterinary medicines, which occurs in man;
- An adverse reaction, which is observed after extra-label use of medicines;
- Lack of expected efficacy possibly indicating development of resistance;
- A problem related to withdrawal periods, possibly resulting from unsafe residues in animal products;
- Possible environmental problems;
- A known adverse reaction mentioned on the package insert, which is serious or which seems to increase in frequency and/or seriousness.

150. If the suspected adverse reaction is serious, particularly if an animal has died, the incident should be reported immediately.

151. It is important that as much detail as possible is reported. If available, laboratory data, post- mortem reports, photographs or other relevant information should be included, and likely differential diagnoses should be considered.

152. Should a pattern of adverse reactions for a specific product emerge, regulatory actions to enhance the safety will be initiated depending on the conditions under which the adverse reactions have appeared and on their seriousness. Examples are:

- Inclusion of warnings on the product label;
- Changes in the authorized use of the product;
- Suspension of the product from the market until the safety issues are solved.

CHAPTER EIGHT

IMPLEMENTATION FRAMEWORK

These guidelines will be implemented by the National government; County governments; Veterinary Medicines Directorate, Kenya Veterinary Board, training institutions; research organizations; the pharmaceutical industry, Private Animal Health Service Providers, animal feed manufacturers, and animal keepers.

Each institution or level of government is expected to avail adequate resources to perform its roles. Such resources shall include staff; equipment; operation costs; building and transport infrastructure and budgetary allocation.

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