Food and Agriculture Organization of the United Nations

VETERINARY MEDICINES DIRECTORATE

BASELINE SURVEY REPORT

Baseline Mapping of the 2017 Veterinary Medicinal Products Supply Chain in Kenya

November 2018

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(GCP/GLO/710/UK)

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Acknowledgement

The baseline mapping of the 2017 veterinary medicinal products supply chain in Kenya was supported by the Fleming Fund through a grant provided to the Food and Agriculture Organization of the United Nations (FAO). We also acknowledge funding received from the United Kingdom (UK) Medical Research Council and CGIAR Research Program on Agriculture for Nutrition and Health (A4NH) that was provided by the International Livestock Research Institute and University of Liverpool to support data analysis. The collaborative efforts of the Veterinary Medicine Directorate (VMD) and FAO staff is highly appreciated. Special gratitude to Stella Kiambi (FAO), Stephen Gikonyo (FAO), Tabitha Kimani (FAO), Naphtal Mwanziki (VMD) and Emily Muema (VMD). Data collection efforts of Hezbon Amenya (DVS), Eunice Omondi (DVS), Adelaide Ayoyi (VMD) and Jane Lwoyero (VMD) is recognised. We appreciate the veterinary pharmaceutical supply chain stakeholders who participated in the one-day consultative meeting and the five-day validation workshop. We are grateful to the study participants who voluntarily participated in the study and provided information that enabled an in-depth understanding of the veterinary medicinal product supply chain in Kenya. We appreciate the contributions of Nicholas Borr who entered the hard copy data into excel worksheets and Henry Mwololo who supported data cleaning, coding and analysis. We are indebted to Pauline Gitonga who analysed the data, interpreted the results and drafted the report.

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Abbreviations

AI	Active Ingredient
AMR	Antimicrobial Resistance
AMU	Antimicrobial Use
DVS	Directorate of Veterinary Services
FAO-UN	Food and Agriculture Organization of the United Nations
GAP	Global Action Plan
KAP	Knowledge, Attitude and Practices
KenTrade	Kenya Trade Network Agency
KRA	Kenya Revenue Authority
LMIC	Low- and Medium-Income Countries
NAP	National Action Plan
NASAC	National Antimicrobial Stewardship Advisory Committee
OIE	World Organisation for Animal Health
PCPB	Pest Control and Poisons Board
PPB	Pharmacy and Poisons Board
UN	United Nations
VMD	Veterinary Medicine Directorate
VMP	Veterinary Medicinal Products
WHO	World Health Organization

Glossary of terminologies[1]

Active ingredient- part of a chemical compound responsible for the antimicrobial action of a veterinary medicinal product. The name used to refer to an antimicrobial agent listed on the OIE List of antimicrobial agents of veterinary importance is generally identical to the active ingredient of that agent.

Antimicrobial agent- are naturally occurring, semi-synthetic or synthetic chemical substances that exhibits antimicrobial activity (kill or inhibit the growth of micro-organisms) at concentrations attainable in vivo. Anthelmintics, acaricides and substances classed as disinfectants or antiseptics are excluded from this definition.

Antimicrobial classes for use in animals- any antimicrobial agent belonging to the antimicrobial classes listed on the OIE List of antimicrobial agents of veterinary importance is included. In addition, antimicrobial agents used exclusively for growth promotion are also included. With the exception of ionophores, which are mostly used for parasite control, all uses of these substances should be reported, whether the antimicrobial agents are categorised as veterinary medicines or not.

Antimicrobial Sales - refers to quantities of antimicrobial agents imported and/or sold within a country for use in animals. Sales data is used as an approximation of actual use.

Antimicrobial use (AMU)- is used in this study to mean the volume of antimicrobials delivered for intended consumption. This does not reflect the actual amount of antimicrobial administered into food animals.

Extrapolation- an approach by which the total amount of antimicrobial agents used in animals was derived from a limited, but representative dataset. Details on the approach should be provided. Caution should be exercised in situations where the data sources are not representative of the whole. For example, extrapolation from a limited number of wholesalers may not adequately represent the entire antimicrobial sales market.

Monitoring: the intermittent performance and analysis of routine measurements and observations, aimed at detecting changes in antimicrobial efficacy and development of resistance in a population.

1Glossaries of the OIE Terrestrial Code and the OIE Aquatic Code (2018)
http://www.oie.int/fileadmin/Home/eng/Health_standards/tahc/current/glossaire.pdf

Quantitative data- 'quantitative' refers to a type of information based in quantities or else quantifiable data (objective properties) — as opposed to 'qualitative' information which deals with apparent qualities (subjective properties). Quantitative data may also refer to mass, time, or productivity. In the context of this report quantitative data means the amount of antimicrobial agents used in animals can be determined, for example through information on amount of antimicrobials imported, or number of packages of specific antimicrobial products used in animals, and is reportable in the metric 'kg antimicrobial agent'.

Surveillance: the systematic ongoing collection, collation, and analysis of information related to AMU and AMR and the timely dissemination of information for action.

Target Veterinary Medicinal Products- the baseline mapping study focused on three types of VMP antibiotics, anthelmintics, ectoparasiticides and antiprotozoal

Therapeutic use- administration of an antimicrobial agent to animals to prevent, control or treat infection or disease.

Veterinary medicinal product- these are natural or synthetic chemical substances with approved claim(s) to having a prophylactic, therapeutic or diagnostic effect or that alter physiological functions when administered or applied to an animal.

Veterinary Authority: the Governmental Authority of a Member Country, comprising veterinarians, other professionals and paraprofessionals, having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the Terrestrial Code in the whole territory.

Veterinary legislation: laws, regulations and all associated legal instruments that relate to the veterinary domain.

Veterinary Services: the governmental and non-governmental organisations that implement animal health and welfare measures and other standards and recommendations in the *Terrestrial Animal Health Code* and the OIE *Aquatic Animal Health Code* in the territory. The Veterinary Services are under the overall control and direction of the Veterinary Authority. Private sector organisations, veterinarians, veterinary

paraprofessionals or aquatic animal health professionals are normally accredited or approved by the Veterinary Authority to deliver the delegated functions.

Executive Summary

The main mandate of the Veterinary Medicine Directorate (VMD) of Kenya is to ensure that Veterinary Medicinal Products (VMP) that are locally manufactured, imported, exported and distributed in the country meet the highest standards of safety, efficacy and quality. To support this mandate VMD was supported by Food and Agriculture Organisation (FAO) through the Fleming fund to design a baseline mapping study that aimed at identifying the source, type, quantity and distribution channels of Veterinary Medicinal Products (VMP) in Kenya. The target VMP included in the study included antibiotics, anthelmintics, antiprotozoal and ectoparasiticides. The target VMP were selected due to scientific and anecdotal reports that document increased incidences of resistance in the country. The results from the study will inform VMD as it establishes a data base on veterinary Antimicrobial Use (AMU). Once established, the AMU database will allow VMD to carry out its pharmacovigilance and post market surveillance mandate as well as contribute data to the national integrated AMR surveillance database. The objectives of the baseline mapping study were to Identify the types and quantities of active ingredient in kilograms of target veterinary medicinal products imported and distributed for sale in the country. The target study population was mainly VMP supply chain actors that is importers/wholesalers, feed millers, retailers, private animal health practitioners and farmers in five counties of Kajiado, Kiambu, Marsabit, Nairobi and Nakuru. The Knowledge, Attitude and Practices (KAP) on Antimicrobial Use (AMU) and Antimicrobial Resistance (AMR) was also assessed at retailers, private practitioners and farmer levels. The study also aimed at documenting regulation compliance barriers and other operation challenges at each level of the VMP supply chain. The study used a participatory data collection approach where stakeholders were involved at each stage of the study. The study was carried out in four stages; Stage 1 was a stakeholders consultative meeting; Stage 2 was a cross-sectional survey that was Informed by the findings of the stakeholders meeting; Stage 3 was analysis of the 2017 National level VMP import data sourced from the Kenya Trade Network Agency (KenTrade) database and stage four was a stakeholder validation workshop.

The study findings revealed that the most common port of entry for VMP products was by sea (98%) thorough the port of Mombasa and by air (2%) through Jomo Kenyatta international (JKIA) airport. Based on the KenTrade data, 17 out of the 30 VMD registered veterinary importing companies requested to import 25 types of Veterinary Medicinal Products (VMP) in 2017. All the products were imported as finished products. The total quantity in Kilograms (Kgs) of all VMP imports was 589,098 kgs, of these 53% (313,447

Kgs) were antibiotics, 43% (255,963 Kgs) ectoparasiticides, 3% (16,402 Kgs) anthelmintics and 1% (3,286 Kgs) antiprotozoal. All antibiotic formulations requested for importation into the country were finished products and were mainly (72%) injectable preparations indicated for the parenteral route of administration. Tetracyclines with 199,568 Kgs was the highest quantity of antibiotic class imported in 2017. Other classes include Salinomycin with 62,310 Kgs, Aminoglycosides with 24,761 Kgs and Penicillins with 18,334 Kgs. The KenTrade acaricide and pesticide data set was integrated with the Pest Control and Poisons Board (PCPB) data from KRA. It was found that only four types of ectoparasiticides were imported in 2017, these included Organophosphate (188,300Kgs); Amitraz (80,297 Kgs), Pyrethroids (31,096 Kgs) and Carbamate (18,700 Kgs).

The main anthelmintic classes requested for import in 2017 included oral benzimidazoles mainly albendazole (7,499 Kgs), Salicylanilide mainly closantel (4,051 Kgs) and Levamisole (3,949 Kgs). Ivermectin (898 Kgs) alone or in combination with closantel was the main injectable anthelmintic product. The main antiprotozoal product was Diminazene aceturate- Berenil (1,299 Kgs). A total of 355 respondents were sampled during the baseline survey, of these 143 were retailers, 139 farmers, 46 private practitioners, 14 VMP importers and 13 livestock feed millers. Bureaucratic procedure in dealing with many national and county level government regulating agencies and the high cost of obtaining GMP certification was the main operation challenge mentioned by VMP importers sampled. Most (125) of the 143 veterinary medicine retail outlets sampled were agrovet enterprises mainly (68) owned by animal health certificate holders. Tetracycline were the highest sold antibiotic class with sale quantities of 554.77 Kgs per month. It also had the highest quantities sold in its parenteral form (311.84 kgs), oral form (228.51 kgs) and topical (13.86 Kgs). Other parenteral antibiotic classes with quantity sales of more than 100 Kgs were Aminoglycosides (171.37Kgs) and Penicillins (160.20 Kgs). Antibiotic classes with quantity sales of less than 10 Kgs were Cephalosporins (8.04 kgs), Trimethoprim (3.98 kgs) and Thiamphenicol (0.70 Kgs). About half (55;51%) of the retailers purchased antibiotics supplies exclusively from pharmaceutical companies while 34 (32%) indicated they purchased from other agrovets. The retailers indicated that animal health practitioners (65) with or without clinics were their main customers who purchased injectable antibiotics. Other customers were livestock keepers (27) from pastoralist production systems and farmers (8) from intensive production systems.

Assessment of AMR knowledge at retailers' level indicated that close to half (46%) of the respondents were knowledgeable about AMR with 66 retailers defining it as when bacteria are resistant to antibiotics. Retailers indicated that they mainly dispensed antimicrobials for management of poultry diseases. The main poultry diseases

encountered included, fowl pox, New Castle Disease (NCD) and Chronic Respiratory Disease (CRD). In cattle and small ruminants, the main diseases were tick borne infections (East Coast Fever), Pneumoniae (CCPP and CBPP) and notifiable disease such as Foot and Mouth disease. The VMP used by all 45 practitioners that had quantities of greater than 1 kg per month were tetracyclines (17 Kgs), Sulfonamides (14 Kgs), benzimidazoles (7 Kgs), penicillins (4 Kgs), macrolides (3 Kgs) and aminoglycosides (3 Kgs). Most (30) private practitioners considered AMR as a very serious problem. The most common livestock disease managed by private practitioners were tick borne infections. The study sampled more (95 of 139) farmers from the extensive/pastoralist production system. Overall the 139 farmers surveyed used a monthly total of 23.67 Kgs of tetracyclines and 9.36 Kgs of Penicillins. The main anthelmintic compound used was albendazole at 8.3 kgs per month. Improper dosage and misuse of drugs was the main reason given by 39% (54) of farmers as causing treatment failures. The use of a country's veterinary medicinal products imports and sales data has been shown to be an effective starting point to quantify AMU in food animals. AMU surveillance and trend monitoring are widely acknowledged as critical components in the response of Antimicrobial resistance (AMR) as well as being effective strategies to quantify the risk of developing and spreading antibiotic resistance in the food-chains. However, many Low- and Middle-Income countries (LMICs) lack or have weak systems for collecting and analysing data on AMR and AMU as they lack resources, have weak laboratory infrastructure and few trained personnel.

The resistance patterns of acaricides and anthelmintics products in Kenya is hardly known due to scanty and far between research and efficacy studies. However, since 2011 antibiotic resistance research in the livestock sector has gained momentum and it is projected to increase following the national focus on tackling AMR. The mapping study found that the trend of importing specific antibiotic classes that is tetracyclines, aminoglycosides and penicillins was similar to the one reported in 2001 in Kenya and in global reports from the European Union member countries. Tetracycline is still the highest imported class of antibiotics. VMD will have to conduct more pharmacovigilance studies to understand if the reported diseases especially tick-borne disease in cattle, mycoplasma infections in cattle, goats and poultry are still sensitive to tetracycline-based products. The baseline mapping survey respondents noted that the main hindrance to compliance was the cost required to acquire legal licenses to import, retail or set up veterinary practices. In addition, the lack of prosecution of defaulters discouraged most actors and hence increased incidences of non-compliance for new entry actors in the supply chain. This means that in Kenya, as in most LMICs, the main barrier to compliance is not lack of legal or regulatory framework but the lack of human and financial resources to enforce these policies and to impose penalties on defaulters.

In conclusion, the current efforts made by VMD to set up a surveillance system on antibiotic use in food producing animals is a step in the right direction and should be

supported. However, in order for the surveillance data to be effective VMD needs to take into consideration the following recommendations:

In the short term,

1. There is an urgent need to streamline the bureaucratic process of acquiring multiple licences and certification at national and county level. VMD should spearhead discussions on this at national and county level.
2. Future AMU surveys should engage a multi-disciplinary team from the start composed of IT experts, social scientist, statisticians and animal health professionals. This will ensure a more robust and inclusive sampling procedure, standardised and digitalised data collection tool.
3. The veterinary medicine directorate will need to spearhead harmonisation of VMP import data at KenTrade as well as lobby for linking of KRA customs data with KenTrade and VMD data bases. This will allow VMD to accurately capture and track VMP imports.
4. The human and veterinary medicine regulatory agencies need to lobby for enforcement of existing laws that advocate for prescription dispensing of human and veterinary antibiotics.

In the long term

1. The veterinary medicine directorate should hire more staff, train them on inspections and devolve them to counties to ensure prosecution of unqualified persons running unlicensed VMP retail outlets.
2. The VMD should foster partnership with research institutions and animal health professional associations to develop treatment protocols for notifiable livestock disease. The protocols should clearly outline first, second and last resort line treatments for each disease. VMD should also spearhead the development of a Kenya Veterinary Medicinal Products handbook or Kenya Veterinary Medicines Formulary.
3. Promote public-private partnerships to conduct continuous surveillance and efficacy trials on acaricides and anthelmintic.

1.0 Introduction

Veterinary Medicinal products (VMPs) are natural or synthetic chemical substances that kill or inhibit growth of animal pathogenic microorganisms and parasites such as bacteria, viruses, fungi, ticks, fleas and helminths. Most VMPs are antimicrobials agents that include antibiotics, antivirals, antifungals and antiprotozoal[2]. Use of antimicrobial agents in livestock production has for decades, supported increased productivity, commercialisation and intensification of food-animal production by facilitating early weaning, increased milk, egg and meat production and promotion of animal welfare[3]. Availability and effectiveness of VMPs is critical to not only animal production and welfare but also to national wealth creation, food security and sustainable animal production[4]. However, these notable gains derived from VMP use have come with negative consequences to animal health and public health. This is mainly attributed to the fact that antimicrobial agents used to treat various infectious diseases in animals and plants are the same or similar to those used in humans and therefore their effectiveness in both sectors is linked.

Specifically, overuse and misuse of antimicrobial agents in humans, animals and plants has been linked to the acceleration of the natural evolutionary processes by which microbes become resistant to antimicrobial treatments[5,6]. Antimicrobial Resistance (AMR) occurs when microorganisms such as bacteria, viruses, fungi and parasites change in ways that make treatment ineffective. The amounts and patterns of Antimicrobial Use (AMU) specifically, antibiotic agents in human and animal health has been identified as a major driver in the selection and propagation of resistant bacteria in both livestock and humans[7, 8].The transfer of resistant zoonotic microbial agents between humans and

2 The OIE Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials (2016). Available from http://www.oie.int/amrstrategy

3 The FAO Action Plan on Antimicrobial Resistance 2016-2020. Supporting the food and agriculture sectors in implementing the Global Action Plan on Antimicrobial Resistance to minimize the impact of antimicrobial resistance. Available from http://www.fao.org/3/a-i5996e.pdf

4 The FAO Action Plan on Antimicrobial Resistance 2016-2020. Supporting the food and agriculture sectors in implementing the Global Action Plan on Antimicrobial Resistance to minimize the impact of antimicrobial resistance. Available from http://www.fao.org/3/a-i5996e.pdf

5 Antimicrobial resistance global report on surveillance (2016-2017). A report by world Health Organisation Global Antimicrobial Resistance Surveillance System (GLASS). Available from http://apps.who.int/iris/bitstream/10665/259744/1/9789241513449-eng.pdf

6 The OIE Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials (2016). Available from http://www.oie.int/amrstrategy

7 Levy, S. B., G. B. FitzGerald, and A. B. Macone. 1976. Changes in intestinal flora of farm personnel after introduction of a tetracycline-supplemented feed on a farm. New England Journal of Medicine 295(11):583–588.

8 Spellberg, B., G. R. Hansen, A. Kar, C. D. Cordova, L. B. Price, and J. R. Johnson. 2016. Antibiotic resistance in humans and animals. Discussion Paper, National Academy of Medicine, Washington, D C. Available from http://www.nam.edu/antibiotic-resistance-in-humans-and-animals

animals occurs through a variety of routes with most research linking the food-borne route as the most important[9].

As a result, drug resistant microbes increase healthcare costs, animal and human mortality and morbidity across the world. Globally the burden of AMR has been estimated at around 700,000 human deaths annually and is projected to rise to 10 million by 2050 if no action is taken to reverse AMR[10]. The AMR burden is particularly relatively higher in Low- and Medium-Income Countries (LMICs) where regulation, surveillance and monitoring systems are weak or lacking. Furthermore, antimicrobial use is projected to increase in LMICs due to the expected rapid growth in human and animal populations and the increasing demand for animal source foods driven by increase in per capita incomes. In addition, LMICs have high incidences of infectious diseases coupled with weak laboratory services.

Concerted global efforts to address AMR earnestly begun in the last 5 years with the development of Global Action Plan (GAP) on AMR in 2015[11] by World Health Organization (WHO) with inputs from the Food and Agriculture Organization of the United Nations (FAO-UN) and the World Animal Health Organization (*OIE*). The GAP calls for a One Health (OH) approach to tackle the global public health threat of AMR. All FAO/*OIE*/WHO member countries committed to institute a multi sectoral or OH approach to combat AMR beginning with development (by 2017[12]) and implementation of national action plans (NAPs). Amongst other activities, GAP advocates for national investment in Antimicrobial Use (AMU) surveillance as a basis of monitoring global trends in use and linking use to AMR patterns. Specifically, public sectors are expected to undertake antimicrobial monitoring and surveillance supported by good stewardship and training[13]. To ensure sustainability of AMU monitoring and surveillance systems, countries are expected to set in place long-term commitments to ensure substantial change in patterns of antimicrobial use is achieved[14].

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9 Brad Spellberg, Gail R. Hansen, Avinash Kar, Carmen D. Cordova, Lance B. Price, and James R. Johnson (2016). Antibiotic Resistance in Humans and Animals. A discussion paper by National Academies of Sciences. Available from https://nam.edu/wp-content/uploads/2016/07/Antibiotic-Resistance-in-Humans-and-Animals.pdf

10 World Health Organization (WHO). Global action plan on antimicrobial resistance (2015). Available from: http://apps.who.int/iris/bitstream/10665/193736/1/9789241509763_eng.pdf?ua=1

11 World Health Organization (WHO). Global action plan on antimicrobial resistance (2015). Available from: http://apps.who.int/iris/bitstream/10665/193736/1/9789241509763_eng.pdf?ua=1

12 https://www.who.int/zoonoses/MoU-Tripartite-May-2018.pdf

13 Monitoring global progress on addressing antimicrobial resistance: Analysis report of the second round of results of AMR country self-assessment survey 2018. Published by the Food and Agriculture Organization of the United Nations, World Organisation for Animal Health and World Health Organization. Available from http://www.who.int/antimicrobial-resistance/publications/Analysis-report-of-AMR-country-se/en/

14 Seale AC, Gordon NC, Islam J et al. AMR Surveillance in low and middle-income settings - A roadmap for participation in the Global Antimicrobial Surveillance System (GLASS) [version 1; referees: 3

In response to the global call for development and implementation of NAPs, the Kenya government in 2014 tasked the Ministry of Health (MOH) and Ministry of Agriculture, Livestock and Fisheries (MALF) to form a National Antimicrobial Stewardship Advisory Committee (NASAC). The NASAC provided a platform for multi-sectoral coordination for the AMR agenda and was instrumental in the development of the national policy and National Action Plan (NAP) of 2017 to 202215. The guiding objectives of the AMR policy and NAP are aligned to the five strategic objectives of the global AMR action plan outlined below;

- Objective 1: Improved awareness and understanding of antimicrobial resistance through effective communication, education and training
- Objective 2: Strengthened knowledge base on AMU and AMR through surveillance, research and implementation of the national integrated AMR surveillance strategy and data base
- Objective 3: Reduced incidence of infection through effective sanitation, hygiene and infection prevention and control activities
- Objective 4: Promote prudent use of antimicrobials in human, animal and plant health
- Objective 5: Support sustainable investment in development of new antimicrobials, diagnostic tools and vaccines

A key activity spelt out in the NAP specifically strategic objective 2 is establishment of an AMU surveillance and monitoring system. The Veterinary Medicines Directorate (VMD), a new regulatory agency established in pursuant of CAP 366 (article 39) of the laws of Kenya is responsible for implementation and coordination of this activity. The mandate of VMD is to ensure that locally manufactured, imported, distributed and exported Veterinary Medicinal Products (VMPs) meet the highest standards of safety, efficacy and quality, are safe for use in animals, and are prudently used. Consequently, this will protect Kenya's animal resource base and assure food safety thus safeguarding both public and environmental health as envisaged in the constitution of Kenya[16].

This report is based on a study to map VMP supply chain in Kenya coordinated by VMD with technical and financial support of FAO through the Fleming Fund of United Kingdom's Department of Health and Social Services. The fund also supported the development of the AMR containment national policy and action plan as well as

approved] Wellcome Open Research 2017, 2:92. Available from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5645727/

15 National Policy for the Prevention and Containment of Antimicrobial Resistance, Nairobi, Kenya: May 2017. Available from https://www.medbox.org/national-policy-on-prevention-and-containment-of-antimicrobial-_resistance/download.pdf

16 http://www.vmd.go.ke/downloads/

communication activities to raise awareness and understanding on AMR in the human and livestock sectors[17]

The report is organised in such a way that the rest of the introduction highlights the rationale for the baseline mapping and study objectives; section two presents the approach used as well as the limitations of the study. Section 3 presents the findings while section 4 presents the discussions and conclusions.

1.1 Rationale

An AMR situation analysis conducted in 2011 in Kenya's human health sector documented increasing levels of antimicrobial resistance in key bacterial pathogens including methicillin resistant Staphylococcus aureus (MRSA) in hospitalized patients, reduced susceptibility of community acquired pneumococci and increased resistance to fluoroquinolones during typhoid outbreaks[18]. Similar findings have been observed in the livestock sector with *Escherichia coli* isolates from beef and poultry showing resistant to tetracycline, co-trimoxazole, streptomycin, ampicillin, quinolones and third generation cephalosporins when analysed in vitro at varying frequencies of application[19]. However, the lack of continuous and systematic surveillance of AMU in human and livestock sectors means that the exact burden of AMR in Kenya is unknown.

In response to the AMR national action plan specifically strategic objective 2, the Veterinary Medicine Directorate (VMD) in collaboration with FAO-Kenya and with support from the Fleming fund designed a baseline mapping study that aimed at identifying the source, type, quantity and distribution channels of Veterinary Medicinal Products (VMP) in Kenya. The target VMP included in the study were antibiotics, anthelmintics, antiprotozoal and ectoparasiticides (pesticides).

[17] https://www.flemingfund.org/about-us/ and https://www.flemingfund.org/countries/kenya/

[18] Global Antibiotic Resistance Partnership—Kenya Working Group. 2011. Situation Analysis and Recommendations: Antibiotic Use and Resistance in Kenya. Washington, DC and New Delhi: Center for Disease Dynamics, Economics & Policy. Available from https://www.sciencedirect.com/science/article/pii/S1201971217302266

[19] Kariuki S, et al. FAO/WHO Project Report: Improving Food Safety in Meat Value Chains in Kenya. Food Protection Trends 2013; 33:172-175. Available from http://www.fao.org/fileadmin/user_upload/agns/news_events/AMR_in_Kenya.pdf

The target VMP were selected due to scientific[20,21,22,23] and anecdotal reports[24] detailing the development their increased resistance in the country. The study also documented operation challenges and regulation barriers to compliance at each level of the VMP supply chain. The results from the study will inform VMD as it establishes a data base on Antimicrobial Use (AMU) in animals. Once established, the AMU database will allow VMD to carry out its pharmacovigilance and post market surveillance mandate as well as contribute data to the national integrated AMR surveillance database[25].

1.2 Study Objectives

1.2.1 General Objective

The overall objective of the study was to generate baseline data on the types and quantities of veterinary medicinal products imported and distributed in the country. This will aid VMD better understand the veterinary medicinal product supply chain and support them to make informed decisions when setting up the veterinary antimicrobial use surveillance system.

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[20] Vudriko P, Okwee-Acai J, Tayebwa DS, et al. Emergence of multi-acaricide resistant Rhipicephalus ticks and its implication on chemical tick control in Uganda. Parasit Vectors. 2016;9:4. Published 2016 Jan 4. doi:10.1186/s13071-015-1278-3. Available from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4700616/

[21] Gitau, G.K., Bundi, R.M.,Vanleeuwen, J. & Mulei,C.M., 2014, 'Mastitogenic bacteria isolated from dairy cows in Kenya and their antimicrobial sensitivity',Journal of the South African Veterinary association 85(1). Available from https://profiles.uonbi.ac.ke/cmulei/files/mulei_c_2014_mastitogenic_bacteria_isolated_from_dairy_cows_in_kenya.pdf

22 Waruiru, R.M., Maingi, N., Gichanga EJ. "Prevalence of anthelmintic resistance in sheep in three districts of Kenya.". In: The Annual Scientific Conference of the Faculty of Veterinary Medicine, University of Nairobi. Nairobi, Kenya; 1990 and https://www.sciencedirect.com/science/article/pii/S0304401797001957

23 Chitanga S, Marcotty T, Namangala B, Van den Bossche P, Van Den Abbeele J, et al. (2011) High Prevalence of Drug Resistance in Animal Trypanosomes without a History of Drug Exposure. PLOS Neglected Tropical Diseases 5(12): e1454. https://doi.org/10.1371/journal.pntd.0001454

24 Proceedings of the workshop on the baseline survey on veterinary pharmaceuticals use held on 19th July 2017 at jacaranda hotel, Nairobi, Kenya. Source: Director of Veterinary Services, Veterinary Medicine Directorate (VMD) Section.

25National Policy for the Prevention and Containment of Antimicrobial Resistance, Nairobi, Kenya: May 2017. Available from https://www.medbox.org/national-policy-on-prevention-and-containment-of-antimicrobial-resistance/download.pdf

1.2.2 Specific objectives

The baseline mapping study sought to;

1. Identify the types of veterinary medicinal products (antibiotics, anthelmintics, antiprotozoal and ectoparasiticides) available for sale and distribution in the country through sampling five counties and using secondary information from the KenTrade single window systems that documents national VMP imports;
2. Quantify the Active Ingredients (AI) in kilograms of the target VMP classes across the VMP supply chain actors; Importers/wholesalers, feed millers, retailers, private animal health practitioners and farmers as previously described[26];
3. Assess the Knowledge, Attitude and Practices (KAP) on AMU and AMR amongst the VMP supply chain actors;
4. Document compliance barriers and other operation challenges at each level of the VMP supply chain.

26 Mitema, E.S., Kikuvi G.M., Wegener H.C. and Stohr K (2001). An assessment of antimicrobial consumption in food producing animals in Kenya. Journal of Veterinary Pharmacology and Therapeutics 24: 385-390.

2.0 Methodology

2.1 Data collection approach

The study used a participatory approach where stakeholders were involved at each stage of the study which was conducted in four stages;

Stage 1: Stakeholders consultative meeting

A one-day workshop held with stakeholders to map the veterinary medicines supply chain in Kenya including gathering information on the interaction of supply chain actors, VMP commodity flow and document challenges of operation and barriers to compliance with legal frameworks at each level of the supply chain. The workshop also aimed at identifying the formal and informal entry and distribution channels of VMP in the country.

Stage 2: Cross-sectional survey

Informed by the findings of the stakeholders meeting, a cross sectional survey was designed and carried out. The survey was guided by pre-tested questionnaires (Annex 2-6). The survey targeted all VMD supply chain actors.

The survey sought to collect primary qualitative and quantitative data that was used to;

i. Identify the types of target VMP Active Ingredients (AI) imported and distributed in Kenya;
ii. Quantify at each supply chain level the AI of each VMP category in Kilograms as previously described[27];
iii. Document at each supply chain level the VMP storage, distribution and disposal practices in place;
iv. Assess the supply chain actors' level of AMU and AMR awareness;
v. Document compliance barriers to the set legal requirements as well as identity operational challenges at each level of the VMP supply chain.

Five counties were selected to participate in the cross-sectional survey. The selection of survey sites (Table 1) was based on five-point criteria as outlined below;

i. VMP import and manufacturing hub (Nairobi, Kiambu, Nakuru),
ii. Feed millers hub (Nairobi, Kiambu and Nakuru)
iii. Agro-pastoral and pastoral livestock production systems (Kajiado and Marsabit),
iv. Intensive and semi-intensive dairy and poultry production systems (Nairobi, Kiambu and Nakuru)
v. International boarder entry and exit points (Marsabit and Kajiado)

27 Mitema, E.S., Kikuvi G.M., Wegener H.C. and Stohr K (2001). An assessment of antimicrobial consumption in food producing animals in Kenya. Journal of Veterinary Pharmacology and Therapeutics 24: 385-390.

Stage 3: Analysis of 2017 National level VMP import data

The secondary data was sourced from the Kenya Trade Network Agency (KenTrade)[28] database. KenTrade is a state agency under the National Treasury that is mandated to facilitate cross border trade through establishment and management of the National Electronic Single Window System. The single window system enables pharmaceutical importers who have been cleared by their respective regulatory authorities to apply for import and export clearance through a single platform.

Stage 4: Stakeholder validation workshop

The VMP supply chain stakeholders were invited for a five-day workshop. The agenda of the five-day workshop was to present the 2017 baseline VMP mapping report that presented the cross-sectional survey and KenTrade analysis findings. The stakeholders through group working sessions were able to keenly go through the report, identify gaps and offer additional information to address these gaps. The validation workshop was also used as a platform to suggest data that should be included in the veterinary AMU surveillance tool.

28 https://www.kentrade.go.ke/

Table 1: Description of study sites

Study site	Agro ecological zone[29] (AEZ)	Livestock Production system	Border point	Livestock population numbers		
1. Nairobi	II-III High to medium potential annual rainfall	Urban and peri urban farmers Small holder intensive production of exotic breeds of dairy and poultry	No	**Species**		**Total***
				Cattle		**44,393**
				Goat		**43,171**
				Sheep		**31,252**
				Pigs		**28,463**
				Commercial chicken	312,311	**577,017**
				Indigenous chicken	264,706	
				Camel		**20**
				Nairobi all species		**724,316**
2. Kiambu	II-III High to medium potential annual rainfall	Mixed production (cash and food crops) Small holder intensive production of exotic breeds of dairy cows and poultry	No	**Species**	**Number**	**Total****
				Dairy Cattle	247,706	**288,158**
				Beef Cattle	40,446	
				Chevon/meat goat	81,079	**102,366**
				Dairy goat	21,287	
				Sheep -wool	31,851	**139,605**
				Sheep-hair	107,754	
				Pigs		**52,588**
				Layers chicken	1,068,873	**2,538,359**
				Indigenous chicken	847,056	
				Broiler chicken	622,430	
				Camel		**0**
				Kiambu all species		**3,121,076**
3. Nakuru	III-IV Medium to low potential annual rainfall	Mixed production (horticulture and food crops) Small, medium and large-scale intensive, semi-intensive and ranches	No	**Species**		**Total***
				Cattle		**118,250**
				Sheep		**114,383**
				Goats		**73,950**

29 http://www.infonet-biovision.org/EnvironmentalHealth/AEZs-Kenya-System

Study site	Agro ecological zone[29] (AEZ)	Livestock Production system	Border point	Livestock population numbers		
		production of exotic breeds of dairy, beef, sheep and intensive poultry		Camel		**2**
				Indigenous chicken- 440,796 Commercial Chicken- 303,805		**744,601**
				Pigs		**5,715**
				Nakuru all species		**1,056,901**
4. Kajiado	IV-V Low potential to erratic annual rainfall	Agro pastoral (food crops) and Pastoral production of exotic dairy cows, local and improved breeds of beef cattle, goats and sheep.	Yes	**Specie**	**Number**	**Total ****
				Dairy cattle Beef cattle	151,850 562,170	**714,020**
				Sheep (hair)		**1,076,520**
				Dairy goat Chevon/meat goat	1,840 1,183,660	**1,185,500**
				Broiler chicken Indigenous chicken Layer chicken	509,595 217,436 203,950	**930,981**
				Camels		**146,300**
				Pigs		**30,180**
				Kajiado all species		**4,083,501**
5. Marsabit	V- VI Very low and erratic annual rainfall	Pastoralist/extensive production of local breeds of beef cattle, goats, sheep and camels	Yes	**Species**		**Total***
				Cattle		**424,603**
				Goats		**1,143,480**
				Sheep		**960,004**
				Camels		**203,320**
				Poultry Indigenous- 46,308 Commercial – 4,382 (Layers& Broilers)		**50,690**
				Pigs		**125**
				Marsabit all species		**2,782,222**

* = Source 2009 Population and Housing Census ** = Source 2017 County Livestock production statistics

2.2 Data management and analysis

Primary data from the cross-sectional survey was entered into an excel spreadsheet (Microsoft Office 2013), the KenTrade data was downloaded as an excel worksheet and did not require data entry. Data cleaning for both the survey and KenTrade data sets involved removing entries that were missing information of the Active Ingredient (AI) name, AI concentration strength and packaging sizes or quantities. Where trade names of VMP were entered the data analyst used the internet to get the AI name. Only entries with the target VMP that is antibiotics, anthelmintics, antiprotozoal and acaricides were retained for analysis. The AI quantity for each product was calculated by multiplying the number of packages imported, sold or used by the concentration of active ingredient (strength). In the case of combination preparations, the amount of AI was calculated for all active ingredients. The amount of AI was calculated in kilogram as previously described[30,31]. The cleaned data was then exported to STATA 14 for analysis which was limited to calculations of frequencies, percentages and means. The results were presented in form of charts and tables.

2.3 Study Limitations

1. Secondary data sourced from KenTrade represented VMP import requests. The actual VMP imports that get into the country through formal channels are documented by the Kenya Revenue Authority (KRA). The lack of integration between KenTrade and KRA databases means that the KenTrade data may not have represented actual VMP imports. To address this limitation the validation workshop participants adopted the use of a correction factor previously described[32]. A correction factor of ±1% was proposed to be applied for the KenTrade data set. The correction factor figure was arrived at following discussion with eight importing companies who indicated that on average they imported 95 to 100% of VMP products requested through KenTrade system

30 Mitema, E.S., Kikuvi G.M., Wegener H.C. and Stohr K (2001). An assessment of antimicrobial consumption in food producing animals in Kenya. Journal of Veterinary Pharmacology and Therapeutics 24: 385-390.

31 Guidance for completing the OIE template for the collection of data on antimicrobial agents intended for use in animals. Available from http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/AMR/A_AMUse_Final_Guidance_2017.pdf

32 Mitema, E.S., Kikuvi G.M., Wegener H.C. and Stohr K (2001). An assessment of antimicrobial consumption in food producing animals in Kenya. Journal of Veterinary Pharmacology and Therapeutics 24: 385-390.

2. The KenTrade data did not also capture information on the quantity of VMP exported into neighbouring countries of Uganda, Tanzania, Rwanda, Burundi, South Sudan, Somalia and Zambia after importation. A correction factor of ±20% was proposed to cater for this limitation
3. The VMP sales data reporting period varied, for example, KenTrade data was collected for one year (2017) but feed millers, retailers, private practioners and farmer VMP sales and use data was collected for one month. This variation limited comparison of VMP quantities along the VMP supply chain levels

Ethical policy

All respondents participating in the questionnaire survey signed a consent form (Annex 1). The respondents' personal information such as the name of company or individual name was numerically coded so as not to reveal actual identities.

3.0 Results

3.1 Findings of Stakeholders Consultative Meeting

The meeting was held on 19th July 2017 and brought together 24 participants from different institutions including; Directorate of Veterinary Services (7), Kenya Veterinary Board (1), Veterinary Medicines Directorate (4), University of Nairobi (2), Pharmacy and Poisons Board (1), Food and Agriculture organization of the United Nations (3) and representatives from the private sector dealing with importation, manufacture and distribution of VMPs (6). The opening plenary presentations detailed the importance of gathering data on the usage of Veterinary Medicinal Products (VMP) in Kenya. The need for a better understanding of the VMP supply chain structure, governance, product distribution channels and bottle necks at each supply chain level was also emphasised. The presenters noted that veterinary pharmacovigilance had historically been neglected and they hoped that the new regulatory agency, the Veterinary Medicine Directorate would prioritise this important function. The participants were informed of the progress made by the country in addressing Antimicrobial Resistance (AMR) with the enactment of the national policy on prevention and containment of antimicrobial resistance as well as the development of the national AMR action plan that was aligned to the AMR Global Action Plan (GAP). The participants reactions to the plenary presentations and presenters' responses are summarised below;

a. *Reaction*: Participants requested the DVS to widely share the AMR policy and National Action plan (NAP) to all stakeholders. There was also needed to create awareness on AMR across the VMP supply chain through development of relevant and targeted communication messages.

   Response: An AMR communication strategy had been developed and is in the course of implementation.

b. *Reaction:* The DVS team in charge of residual testing was urged to work together with existing programs such as the European Union (EU) funded Standards and Market Access Program (SMAP). SMAP focuses on monitoring of residues in foods of animal origin and has developed monitoring plans and standards.

   Response: DVS has already developed residue standards for meat, honey and milk.

c. *Reaction:* Participants noted that the increased importation and supply for antimicrobials especially antibiotics was driven by demand from farmers.

   Response: A socio economic study needs to be undertaken to help understand the drivers that lead to the widespread and uncontrolled sale and use of antimicrobials especially at agrovet retailer and farmer levels.

d. *Reaction:* It was noted that diagnosis by animal health practitioners and famers was mainly based on clinical signs. This practice was contributing to overuse and mis-use of antibiotics.

   Response: There is limited access to laboratory diagnostic facilities and where accessible the turn around to get results takes a long time. There is need to create awareness and advocate for use of rapid test kits and encourage laboratories carrying out veterinary diagnosis to set up Quality Management Systems (QMS) so as to ensure cost effective, timely and accurate laboratory diagnosis.

e. *Reaction:* There is no clear guideline on how to collect and where to submit samples for veterinary drug residue testing.

   Response: The DVS with support from AU-IBAR[33] and FAO-UN has developed a veterinary drug residue laboratory policy. The University of Nairobi-department of Pharmacology, Toxicology and Public Health (PHPT), DVS-Central Veterinary Investigation Laboratories (CVIL) and private laboratories such as SGS were identified as laboratories that conduct residue testing.

f. *Reaction*: Once fully operational, the stakeholders expect the Veterinary Medicines Directorate (VMD) to address the following urgent concerns;

- Develop guidelines on how to dispose expired liquid based VMP;
- Develop good distribution practices standards for VMP that should also include transportation and storage guidelines for each VMP category/class;
- Give clear guidelines on importation of veterinary pharmaceuticals. The participants were directed to the VMD website that clearly stipulates the guidelines[34];
- Address the current practice of imposing multiple licences from various national and county government institutions;
- Carry out its pharmacovigilance and post-market surveillance mandate.
- Consultatively spearhead the development of a National Drug Formulary-to guide veterinary practitioners on the required first-line drugs for notifiable or diseases.
- Fast track review of new VMP dossiers some of which will reduce reliance on antibiotics to control infections especially in intensive livestock production systems.

33 African Union Inter-African Bureau for Animal Resources
34 http://www.vmd.go.ke/downloads/

The VMP supply chain stakeholders were grouped according to their level of operation in the supply chain. Through group work sessions and plenary discussions, the stakeholders mapped the VMP supply chain actors, identified formal and informal distribution channels and identified compliance barriers to set regulations and challenges of operation at each supply chain level. A summary of the group's outputs are summarised in the tables below.

The participants identified 27 VMP importers with majority being from the private sector and others from national government or large-scale livestock production farms.

Table 2: Mapping VMP importers and local manufacturers

What type of VMP are imported/manufactured?	VMP entry ports	Where are VMP sold?	How are VMP disposed?	Challenges/ Barriers to regulation compliance
Injectables antibiotics	**Airports –**	Veterinary practitioners	Incineration at KEMRI	Bureaucracy procedure in dealing with many agencies
Oxytetracycline	Jomo Kenyatta International airport	Agrovets	Some companies do self-disposal by incineration	
Penicillin- Amoxicillin	Moi International airport	Pharmacies		Delay in market authorization of new products
Penicillin-streptomycin	Eldoret International airport	NGOs	Informal disposal to garbage dump	
Tylosin		Farmers		To many documentations required and duplication of the documents
Sulphamethazole	**Seaports-**	Institutions -schools, Cooperatives, Farmers/Pastoralists	Disposal companies licensed by NEMA & pharmacy and poisons board	
Sulphamethazole& trimethoprim	Mombasa			Damages and theft of goods on transit
Gentamycin	Kisumu			
Cephalosporins				Lack of raw materials from local source
Soluble antibiotic powders	**Border points (Informal/illegal)**			
Oxytetracycline and Doxycycline	Lungalunga			High taxation on raw materials
Tylosin	Taita Taveta			
Colistin	Namanga			Stringent GMP inspection requirement.
Ampicillin	Isibania			
Quinolones	Malaba			Lack of local availability of raw materials for manufacturers.
Antiprotozoal	Busia			
Homidium	Moyale			
Isometamidium	Mandera			
Diminazene	Lodwar			
Quinapyramine				
Buparvaquone/Parvaquone				
Imidocarb				
Antifungals				

What type of VMP are imported/manufactured?	VMP entry ports	Where are VMP sold?	How are VMP disposed?	Challenges/ Barriers to regulation compliance
Disinfecting Reagents Quaternary ammonium Formaldehyde Iodine Methylated spirit Surgical spirit Hydrogen peroxide	Somali Border Liboi			Most antibiotics come in as finished products Committee responsible for registration of veterinary pharmaceuticals had not met for the past three (3) years.

Participants identified 35 wholesale distributors, most of the importing companies also doubled as wholesale distributors. Other wholesale distributors included agrovet dealers, non-governmental organisations, development partners, large scale livestock production farms, county and national government institutions.

Table 3: Mapping VMP Wholesale distributors

Type of VMP distributed	Source of VMP	Where are VMP sold?	Method of VMP disposal	Challenges of operation and Regulation compliance barriers
Antibiotics	**Formal**	**Local**	**Licenced Incinerators –**	Maintenance of cold chain – especially during transportation and storage
Oxytetracycline/Doxycycline	Importers	FARMS-large scale farms,	MOH and Private sector	
Penicillins	Manufacturers	Institutions, universities, farmer cooperatives, feed millers,	Individual 'incinerators' at business premises	Lack of traceability from source to end user
Sulphonamides				
Cephalosporins				Counterfeit products
Tylosin	**Informal**	**Agrovet/Retailers**	Retailers and agrovets -	
Erythromycin	Most feed millers	Large scale- often mix wholesaling and retail (mostly). 1 or 2 in major towns	Dispose into the environment: poured and disposed among garbage	Poor regulation and enforcement
Ampicillin				
Amoxicillin	Individuals cross-border smugglers (Busia, Namanga, Moyale, Mandera)			Lack of self-regulation – Introduce a Veterinary Pharmaceutical Traders Association
Lincomycin				
Antiprotozoal		Small size agrovet -many Veterinary clinics		
Buparvaquone/ Parvaquone				Poor quality packaging
Imidocarb dipropionate				
Antifungals		**County Governments**		Lack adequate information
Dewormers		DVS,		
Albendazoles				High cost of operation due to the many licences one needs to acquire from county, PPB, Pest Control and Poisons Board (PCPB) and Occupational Safety and Health Act OSHA compliance
Levamisole		**EXPORT:**		
Oxyclonide		Uganda		
Phenbendazole		Tanzania		
Ivermectin		South Sudan		
Amprolium		Ethiopia		
		Somalia		Poor infrastructure especially warehouses and increased power outages hence maintenance of cold chain becomes expensive as they need to use generators
		Burundi		
		Rwanda		

Type of VMP distributed	Source of VMP	Where are VMP sold?	Method of VMP disposal	Challenges of operation and Regulation compliance barriers
				Expensive to hire a veterinary professional to run a wholesale outlet

Table 4: Mapping VMP retailers and consumers in high and medium rainfall potential areas

Retailers	What VMP are sold?	VMP source	Where are VMP sold?	How is disposal done?	Challenges of operation	Regulation compliance barriers
• Agrovets • Practitioners • Cooperative shops • Franchises • Unqualified traders • Farm input shops • Large integrated companies • Vet clinics • Human chemists • Feed shops	• Pen strep • Oxytetracycline • Sulfachloropryzine • Sulfonamides • Tylosin • Trimethoprim • Fluoroquinolones • Amprolium • Medicated feed	***Formal*** • Registered importers • Registered manufacturers • Wholesalers • Other retailers • Briefcase salesman ***Informal*** • Cross border traders • NGOs • Contraband • Cartels	• Farmers • Paravets • Vets • Quacks • NGOs • Government • Institutions • Feed manufacturers • Cross border trade	***Expired drugs*** • Local council • Pit latrine • Incineration • Selling to consumer • Return to source • Gifting • Revalidation	• Lack of product knowledge • Demand driven sales • Lack of laboratory diagnosis • Multiple licensing • Unethical competition • Lack of awareness creation on prudent VMP	• Duplication of licensing (national/county) • Cost of licenses • Lack of Infrastructure • Minimal penalties • Financial greed • Employment of non-professionals • Lack of Training programmes for professionals

Table 5: Mapping of retailers and farmers in Pastoral and Agro-pastoral areas

Retailers	What VMP is sold?	Sources of VMP	Who are VMP sold to?	VMP disposal	Challenges and regulation compliance barriers
• Agrovet run by qualified professionals • Agrovets run by traders • General/mixed traders • Mobile traders/agrovets • Open air hawkers/professionals • CBOs/Pastoral drug users association, groups • NGOs • FBOs • Farmers • Govt animal health professionals • Livestock traders • County governments • Pharmaceutical reps • CBAWs • Community leaders	**Antibiotics** injectables Antibiotics orals Antibiotics topical **Dewormers** Oral dewormers injectables Dewormers pour-on **Antiprotozoal** injectable and oral **Acaricides** Pour-on, Spray dips, injectable Vaccines Antifungals Intramammary Anti-inflammatory Disinfectants Purgatives Absorbents Mineral supplements; Injectables, powders, licks	**Formal** • Pharmaceutical reps • NGOs • Distributors • County • Manufacturers • Agrovets **Informal** • General traders • Livestock traders • Smugglers • Counterfeits • Illegal imports • Informal manufacturing	• Other retailers • Farmers/pastoralists • Animal health service providers • CBAWS • Traders/Brokers • CBOs, DUAs, NGOs • Open air markets • Cross border traders • Livestock markets • Mobile dealers	***Expired drugs*** • Return to supplier • Sell – some unaware of expiries • Alter expiry dates • Dispose in pit together with garbage • Certified hazardous material disposal; use, reward, myth – 6 months grace periods	**Governance** • Cannot meet threshold for licensing due to low purchasing power of customers • Inadequate technical personnel • Remoteness-regulators hardly access • Pricing • Illicit business • Porous borders • Inadequate awareness • Insecurity **Infrastructure** • Cold chain • Road network • Amenities- water, buildings, transport **Culture** • Social value of livestock

Retailers	What VMP is sold?	Sources of VMP	Who are VMP sold to?	VMP disposal	Challenges and regulation compliance barriers
					Self- treatment of livestock by farmers who Poor understanding of camel health and medicine.

The stakeholders were also able to characterise at each level of the supply chain key actors, type of veterinary medicinal product traded and distributed (Figure 1).

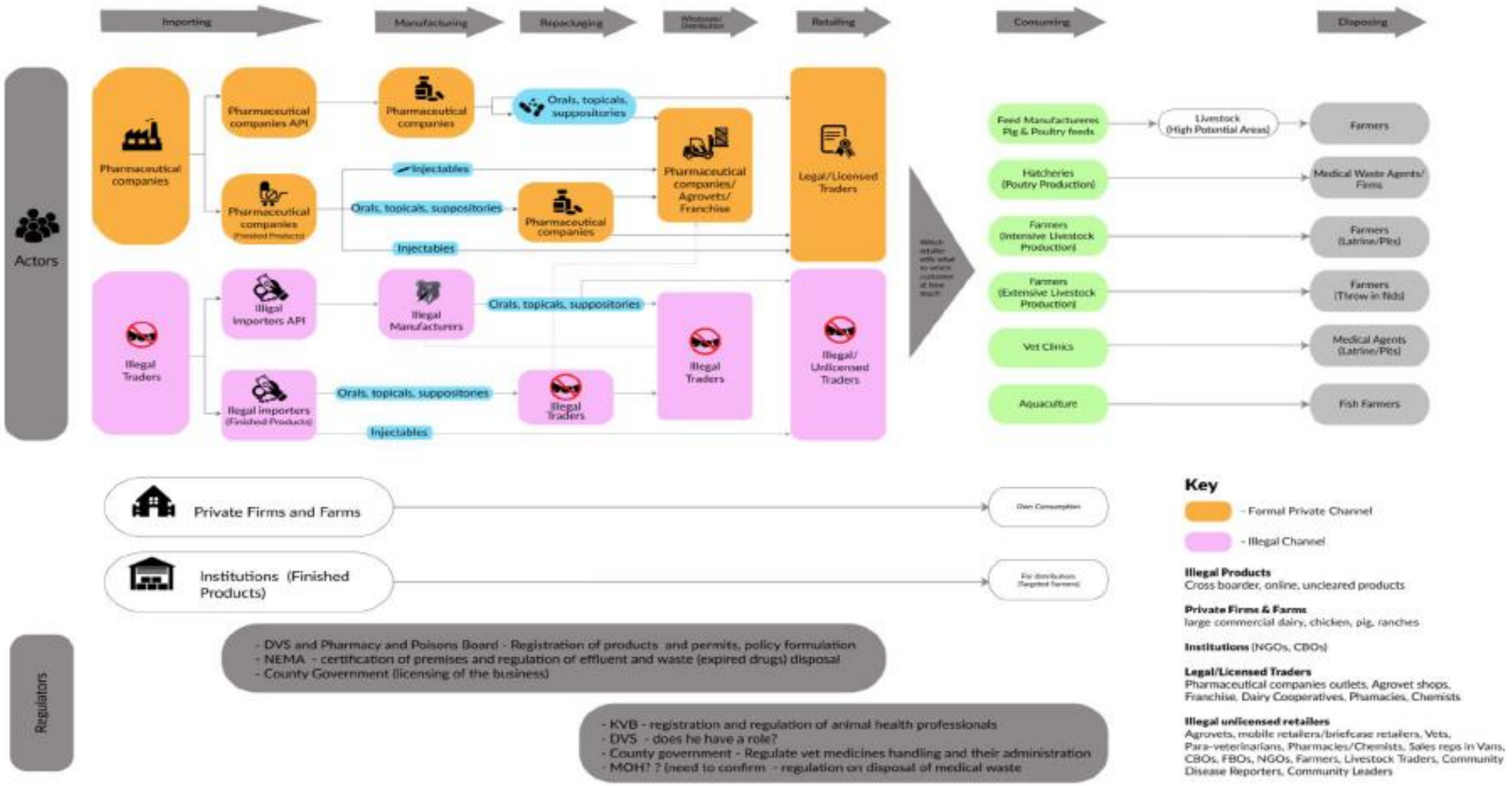


Figure 1: Veterinary medicinal products supply chain structure, governance and distribution channels in Kenya (July 2017).

Stakeholders participating in the one-day consultative meeting also identified critical border entry and exit points (Figure 2). The border points were flagged as high-risk areas for unofficial exit of VMP as well as unofficial entry of counterfeit or unregistered veterinary medicinal products.

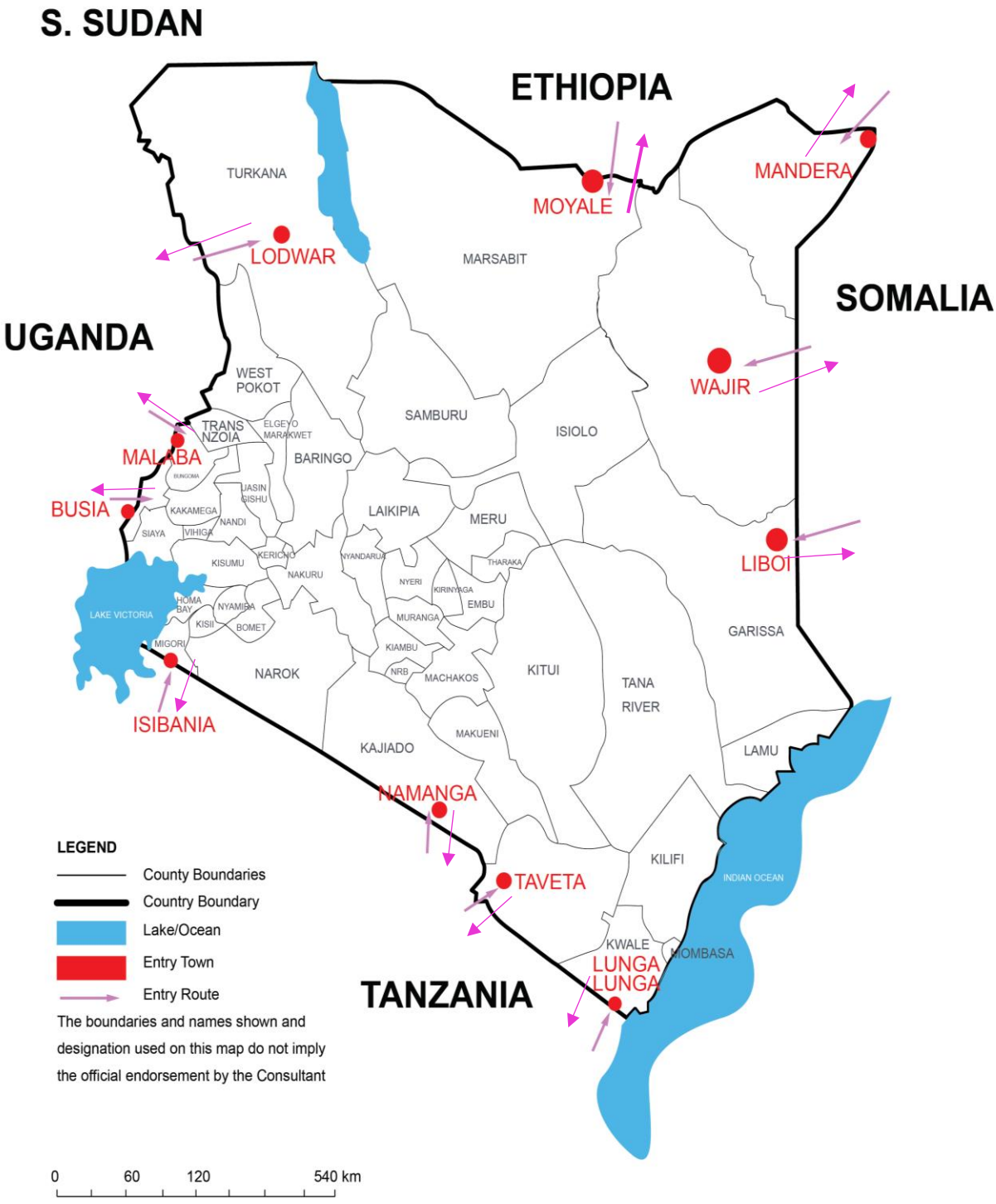
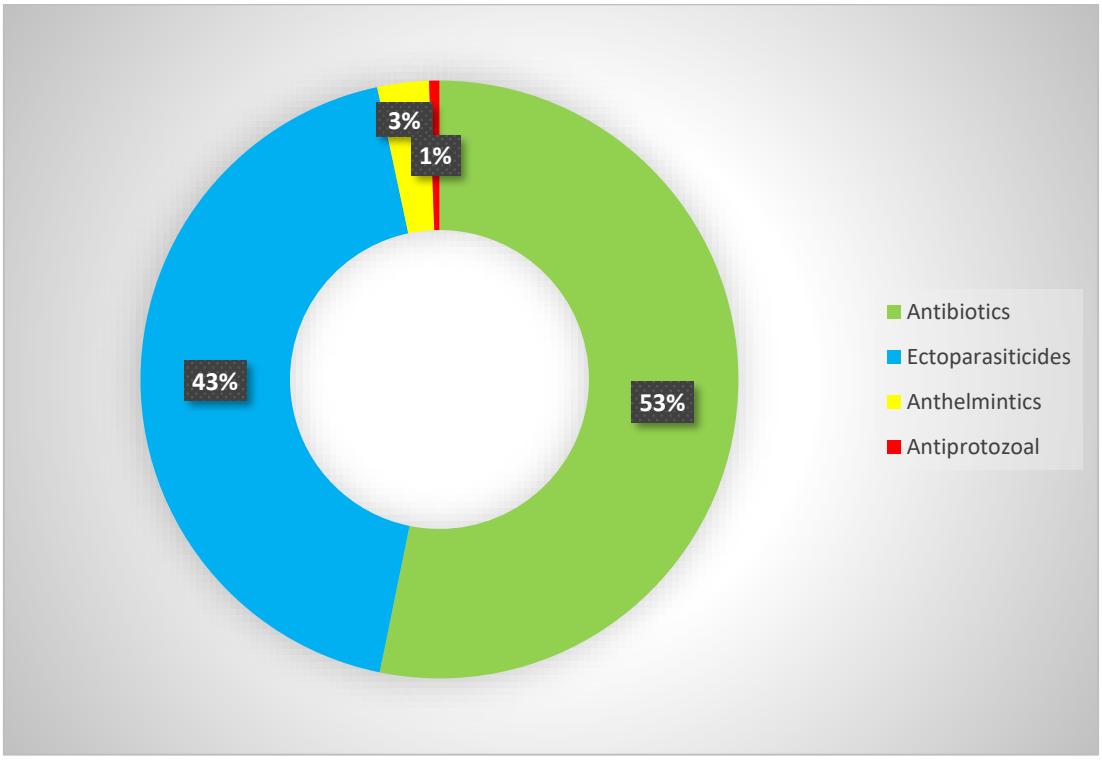


Figure 2: Critical high-risk crossing border points for VMP in Kenya

3.2 Findings: Veterinary Medicinal Products Import Requests

In 2017, a total of 850 entries composed of antibiotics (461), anthelmintics (251), antiprotozoal (72) and ectoparasiticides (66) were entered as import requests in the KenTrade single window system. The total quantity in Kilograms (Kgs) of all VMP imports was 589,098 kgs, of these 53% (313,447 Kgs) were antibiotics, 43% (255,963 Kgs) ectoparasiticides, 3%(16,402 Kgs) anthelmintics and 1% (3,286 Kgs) antiprotozoal (Figure 3).



3.2.1 VMP import requests by country of origin and port of entry

Figure 3: Type of Veterinary Medicinal Products Import Requests in 2017

(Source KenTrade single window system)

The most common port of entry for VMP import requests was by sea (98%) thorough the port of Mombasa and by air (2%) through Jomo Kenyatta international (JKIA) airport. Based on the KenTrade data, 17 out of the 30 VMD registered veterinary importing companies requested to import 25 types of Veterinary Medicinal Products (VMP) in 2017. The imported products included 10 antibiotic classes, 5 anthelmintic groups, 7 antiprotozoal agents and 3 acaricide groups. Most of the VMP were sourced from China that dominated with the importation of 7 of the 25 products, followed by Belgium with 6 and United Kingdom (UK) with 4. The UK was the source country for the three main antibiotic products containing tetracycline, aminoglycosides and penicillin Active Ingredient (AI). China and India were the leading source countries for Amitraz and

Pyrethroids ectoparasiticides respectively. China was also the main source country for albendazole while UK for Levamisole anthelmintics. Korea was the main source country for salinomycin product while China, Belgium and India were the source countries for trypanocidal products.

The cost incurred by importing companies was captured as FOB[35] figures to buyers' destination port as shown in table 6 below. Antibiotics incurred the highest FOB cost

Table 6: Importation costs (FOB to destination port) for VMP (Source KENTRADE 2017)

Type of VMP	Total FOB (US$)
Antibiotic	16,462,961.00
Antiprotozoal	16,431,240.00
Ectoparasiticides	8,845,751.00
Anthelmintic	7,233,043.00

3.2.2 Type and quantity of veterinary antibiotic imports

There were 10 classes of antibiotics requested for importation through the KenTrade system, of these, 64% were from the Tetracycline class of antibiotics (Table 7).

Table 7: Type and quantity of veterinary antibiotic class imports

Antibiotic class	Quantity (Kgs)	Percentage of import request
Tetracyclines	199,568	64%
Salinomycin	62,310	20%
Aminoglycosides	24,761	8%
Penicillins	18,334	6%
Macrolide	4,748	2%
Sulfonamides	2,735	1%
Trimethoprim	412	0.13%
Colistin	471	0.15%
Fluoroquinolones	91	0.03%
Cephalosporins	17	0.01%
Total	**313,447**	

35 FOB stands for "free on board" or "freight on board" and should always be followed with the name of originating port. FOB indicate when liability and ownership of goods is transferred from a seller to a buyer. In most cases the seller (consignor) is responsible for transportation of the goods to the port of shipment he also incurs cost of loading. The buyer (consignee) pays the ocean or air freight costs, insurance, unloading and transportation from the arrival port to the final destination. The seller passes the risk to the buyer when the goods are loaded at the originating port.

All antibiotic formulations requested for importation into the country were finished products and were mainly (72%) injectable preparations indicated for the parenteral route of administration (Figure 4).

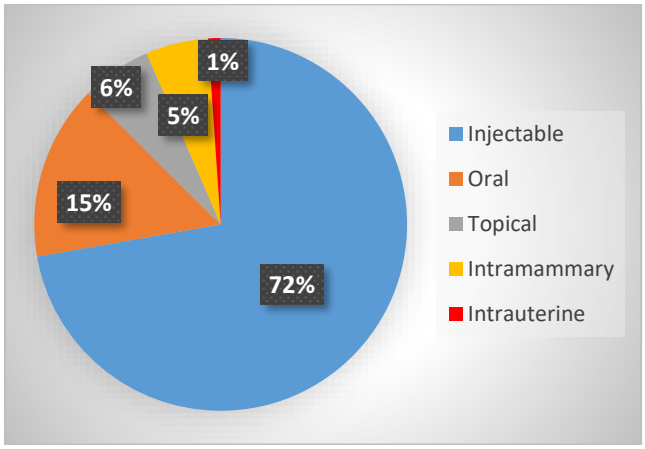


Figure 4: Route of administration forms for imported Veterinary Medicinal Products

(Source KenTrade single window system)

Oxytetracycline was the main injectable, oral and topical Tetracycline molecule. While Doxycycline was the main oral preparation and Chlortetracycline the main intrauterine preparation. Streptomycin and Gentamycin were the main injectable aminoglycoside molecules while Kanamycin and Neomycin were the main Intramammary preparations. Benzyl penicillin and amoxicillin were the main injectable and Intramammary Penicillin molecules while Ampicillin was the main oral preparation. Penicillin and Aminoglycoside based antibiotics were requested as a combined drug called Penstrep®. Tylosin was the main injectable Macrolide while Erythromycin was the main oral preparation. Sulphonamide and trimethoprim were requested as a combined product composed of both injectable and oral preparations. The main Fluoroquinolone import request was Enrofloxacin as an injectables preparation. Cephalexin, a first-generation cephalosporin injectable preparation was the only 2017 Cephalosporin import request. The product was requested as an Intramammary preparation that was combined with Kanamycin, an aminoglycoside molecule.

3.2.3 Type and quantity of veterinary ectoparasiticide imports

There were only three types of ectoparasiticides import requests in 2017, these included Amitraz and Organophosphate acaricides and Pyrethroids. All the three group of products were requested as finished products and were indicated for topical route of application. The quantity and percentage of import request for each group of products is detailed in table 8 below. Organophosphates formed the bulk of acaricide request. During the validation workshop the Pest Control and Poisons Board (PCPB) shared the 2017 acaricide and pesticide import data sourced from Kenya Revenue Authority (KRA). The

quantity differences between the import request and actual imports are shown in table 8 below. The PCPB data from KRA customs office indicated that total actual imports in 2017 were more in all chemical categories. In addition, the KRA custom data was able to capture the carbamate acaricide group which had not been captured in the KenTrade data set.

Table 8: Type and quantity of veterinary ectoparasiticides import requests verses actual imports (source KenTrade and PCPB 2017)

Type of ectoparasiticide (KenTrade import request)	Quantity (Kgs)	Percentage of import
Organophosphate	148,700	58%
Formamidine -Amitraz	77,043	30%
Pyrethroids	30,220	12%
Import request total	**255,963**	
Type of ectoparasiticide (PCPB actual imports)	**Quantity (kgs)**	**Percentage of import**
Organophosphate	188,300	59%
Formamidine- Amitraz	80,297	25%
Pyrethroids	31,096	10%
Carbamate- Carbaryl	18,700	6%
Actual import total	**318,393**	

3.2.4 Type and quantity of veterinary anthelmintic imports

Albendazole was the most common oral anthelmintic product requested for importation while Ivermectin either on its own or in combination with closantel was the most common injectable anthelmintic. The types and quantities of anthelmintic import request are shown in table 9 below.

Table 9: Type and quantity of veterinary anthelmintic imports

Type of Anthelmintic	Quantity (Kgs)	Percentage of import request
Benzimidazoles (albendazole)	7,499	46%
Salicylanilide (closantel, oxyclonazide, Nitroxynil)	4,051	24%
Imidazothiazoles (Levamisole)	3,949	25%
Macrocyclic lactone Ivermectin)	898	5%
Other-Piperazine	5	0.03%
Total	**16,402**	

3.2.4 Type and quantity of veterinary antiprotozoal imports

Most (70) of the 72 entries of antiprotozoal products requested for importation in 2017 were indicated for injectable or parenteral route of administration. The main antiprotozoal product was Diminazene aceturate (Berenil) other products and their quantities are summarised in table 10 below.

Table 10: Type and quantity of veterinary anthelmintic imports

Type of antiprotozoal product	Quantity (kgs)	Percentage of import request
Diminazene aceturate (Berenil)	1,299	40%
Quinapyramine	844	26%
Buparvaquone/ Parvaquone	597	18%
Isometamidium	400	12%
Homidium	134	4%
Toltrazuril and Amprolium	11	0.33%
Imidocarb dipropionate	1	0.03%
Total	**3,286**	

3.3 Findings: VMP supply chain survey and Validation workshop

The cross-sectional baseline mapping survey was carried out in Nairobi, Kiambu, Nakuru, Kajiado and Marsabit counties between August and September 2017. The survey interviews were guided by pre-tested questionnaires. A total of 355 individuals (Table 11) that represented all levels of the VMP supply chain were included in the survey. The survey findings formed part of the report that was presented to stakeholders in a review and validation workshop held on 23rd to 25th October 2018 at Dove Nest lodge Naivasha, Kenya. The validation workshop was attended by 20 participants drawn from the Veterinary Medicines Directorate (VMD), Pest Control Board (PCPB), Veterinary Medicines Importers and Manufacturers Association of Kenya (VISAK), Directorate of Veterinary Services (DVS), University of Nairobi (UoN), Private pharmaceutical companies, representatives from counties samples (Kiambu and Kajiado), International Livestock Research Institute (ILRI), Association of Animal Feed Manufacturers (AKEFEMA), Kenya Livestock Marketing Council (KLMC) and FAO-UN. The report was keenly analysed through group work sessions followed by group presentations and plenary discussions.

Table 11: Sample size of the veterinary medicine supply chain survey in 5 Counties

Respondent category	Number Sampled	Type of data collected	Geographical location (County)
VMP Retailers	143	VMP sales data	Kajiado, Nakuru; Marsabit; Kiambu and Nairobi
Farmers	139	VMP use data	Kajiado, Marsabit, Nakuru and Kiambu
Private practitioners	46		Nakuru, Kajiado, Marsabit, Nairobi and Kiambu
Importers, Manufacturers, Wholesale distributors	14	VMP import and sales data	Nairobi and Nakuru
Feed millers	13	VMP use data	Kiambu, Nakuru and Kajiado
Total	**355**		

The 2017 KenTrade system did not capture actual VMP import and export data. To mitigate this limitation the validation workshop stakeholders proposed the use of a correction factor as previously documented[36]. A combined correction factor of ±21% was proposed that is, ±1% to cater for VMP imports that were not actually imported into the country in 2017 and ±20% for 2017 VMP imports that were exported to neighbouring countries. The estimated actual VMP imports (orange) that were available for sale and use in Kenya in 2017 are shown in figure 5 below.

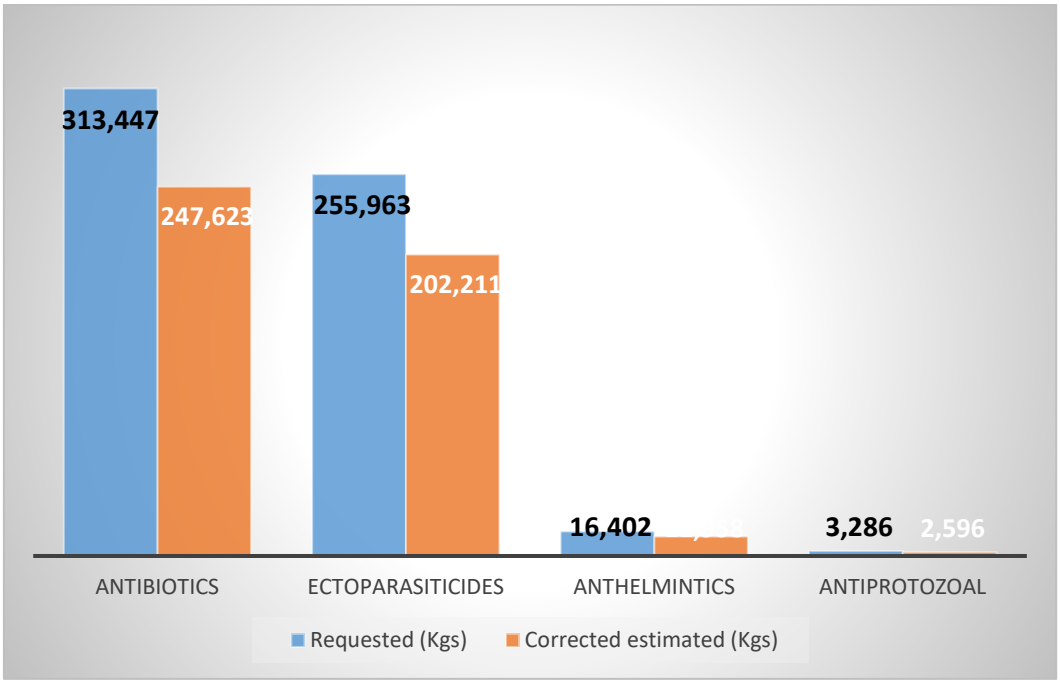


Figure 5: Proposed correction of the 2017 KenTrade VMP Import data

36 Mitema, E.S., Kikuvi G.M., Wegener H.C. and Stohr K (2001). An assessment of antimicrobial consumption in food producing animals in Kenya. Journal of Veterinary Pharmacology and Therapeutics 24: 385-390.

3.3.1 Mapping Importers, manufacturers and wholesale distributors

The cross-sectional survey sampled 14 importers, manufacturers and distributors of veterinary medicinal products. The type of enterprise operation is summarised in table 12 below. The main Veterinary Medicinal Products (VMP) respondents imported and sold through their wholesale distribution channels were antibiotics, acaricides, anthelmintics and antiprotozoal.

Table 12: Type of VMP enterprise at importer, manufacturer and wholesale level

VMP Enterprise	Frequency	County
Importer -Finished VMP & wholesale distributor	9	Nairobi
Wholesale distributor only	3	Nakuru
Manufacturer	2	Nairobi
Total	**14**	

a. Licensing and regulation

The stakeholders indicated that licencing and regulation of veterinary medicinal products was now under the mandate of the Veterinary Medicines Directorate (VMD). However, most workshop participants revealed that in 2017 when the survey was conducted licensing and regulation of some VMP was still under the mandate of the Pharmacy and Poisons Board (PPB) and the Pest Control Products Board (PCPB). The baseline survey revealed that the 14 importing companies required the following licenses to operate;

1. Single business permit;
2. Good Manufacturing Practice (GMP) certificate for manufacturing premises/plant;
3. National Environmental Management Authority (NEMA) authorization;
4. Kenya Veterinary Board (KVB) certificate;
5. Wholesaler Dealer License (WDL);
6. PCPB certification;
7. Health certification.
8. Marketing authorization for each product (Certificate of Registration)

More than half (8) of the survey respondents indicated they had health certificates while half (7) had GMP certificates. Only 8 of the 12 that were conducting wholesale distribution had obtained WDL. The survey also sought to know how easy it was to acquire the above listed licenses, 9 of the respondents indicated that it was easy while 5 indicated that it was difficult to acquire GMP. The validation workshop participants detailed the cost of doing business (Table13), with particular reference to cost incurred to meet the regulatory and statutory licences requirements as at 2017.

Table 13: Regulation cost incurred by importers, manufacturers and wholesale distributors (Source validation workshop 2018)

Type of License	Licensing Authority/ Duration of license	Manufacturer	Importers	Wholesale distributor
Single Business Permit	County Governments (1yr)	Kshs. 100, 000	Kshs. 15, 000 – Ksh. 40, 000	Ksh. 15, 000 – Ksh. 40, 000
License to Manufacture	VMD/PPB (1yr)	Kshs. 30, 000	N/A	N/A
Wholesale Dealers License (WDL)	VMD/PPB (1yr)	Kshs. 30, 000	Ksh. 30, 000	Ksh. 30, 000
Market Authorization (Certificate of Registration)	VMD/PPB (Initial)	USD 1000 (Foreign) USD 500 (Local)	USD 1000	N/A
	VMD/PPB Retention: (Annually)	USD 300	USD 300	
GMP License (Premises)	VMD/PPB (3 Years)	USD 1000 (Local) USD 4000 (Foreign)	USD 4000 (Foreign)	N/A
Environment Impact Assessment (EIA)	NEMA	Ksh. 20, 000 – Ksh. 30, 000	Ksh. 20, 000 – Ksh. 30, 000	N/A
Food and Drug ACT (Cap. 254) - Health	County Government	Ksh. 15, 000 – 20, 000	Ksh. 15, 000 – 20, 000	
Kenya Veterinary Board (KVB)	KVB (Annually)	Responsible personnel - Ksh. 4, 000	Responsible personnel - Ksh. 4, 000	Responsible personnel - Ksh. 4, 000
Kenya Veterinary Association (KVA)	KVA (Annually)	Responsible personnel - Ksh. 2000	Responsible personnel - Ksh. 2000	Responsible personnel - Ksh. 2000
Kenya Veterinary Board (KVB) Practice License	KVB (Annually)	Ksh. 8, 000	-	-
PCPB Premise License	Distribution/wholesale: Repacking Formulation/manufacture: Storage/warehouse:	Ksh. 4,000 - Ksh. 7500 Ksh. 5000	Ksh. 4, 000 Ksh. 5,000 - Ksh. 5000	Ksh. 4, 000 - -
PCPB Product Certificate of Registration	Registration (3 years)	Ksh. 30, 000	Ksh. 30, 000	N/A
	Renewal (Every 2 years)	Ksh. 20, 000	Ksh. 20, 000	

b. Annual import quantity of VMP

Only 7 of the 14 respondents accurately provided information to allow calculation of VMP quantities. A summary of VMP types and quantities are shown in figure 6 below. The data captured did not allow disaggregation of data into their respective AI/chemical groupings.

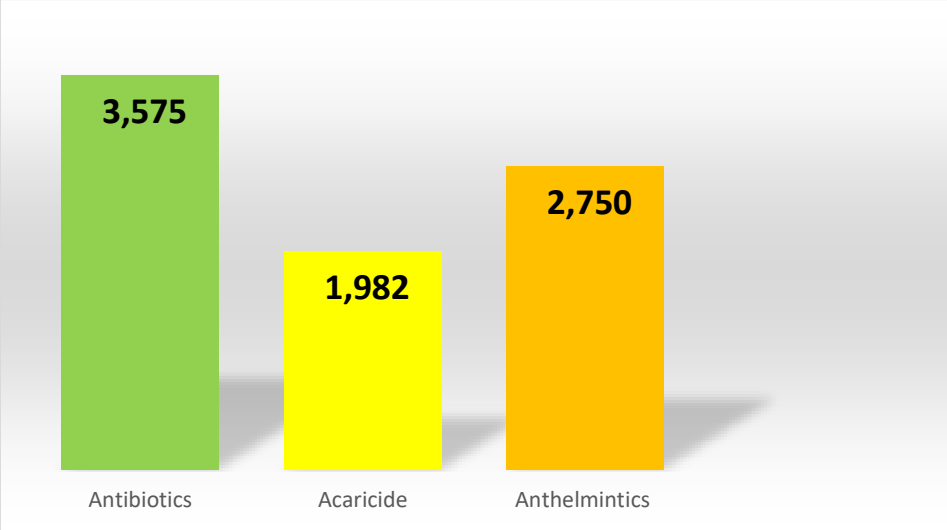


Figure 6:Type and quantity of VMP at importer, manufacturer and wholesaler distributor level

c. Internal quality control system

The survey determined the quality control processes put in place by importing and wholesale distributor companies. Most (10) of the 14 survey respondents indicated they had a computer system that tracked stock. In addition, the software also red flagged stock that had a short expiry period or had expired so as to allow the company to sell the product before the expiry period or dispose expired drugs. Majority of importers indicated they stored all types of pharmaceutical products in one warehouse with only 5 of the 14 indicating they separated pharmaceutical products based on their chemical groups or target consumers (human or veterinary). All 14 importers restricted access to their warehouse premises especially for high value products such as vaccines and hormones. All 14 importers also indicated they had a quarantine plan in place for expired, damaged or recalled products. Most (11) importers had temperature monitored and controlled stores/warehouses. Almost all (12) indicated they had a pest management plan in place. The following were the actions taken by importers to dispose expired products; Return to supplier (3); Dispose in a pit (1); Take to KEMRI, NEMA or PPB for incineration (6); Contract private company to dispose (3);Give as free samples (1). The Knowledge, Attitude and Practices (KAP) on veterinary Antimicrobial Use (AMU) and Antimicrobial Resistance (AMR) was not assessed at this level. The validation workshop participants reviewed and enriched the survey responses on challenges of operation and barriers to compliance to set regulation. A summary of the survey findings and validation workshop discussions are highlighted in table 14 below.

Table 14: Challenges of operation and regulation compliance barriers at importer, manufacturer and wholesale distributor level

	Challenges /Regulation compliance barriers	Thematic area	Possible solution
1.	Bureaucratic procedure in dealing with many government regulation agencies. This has resulted in delays in obtaining licenses and certification and duplication of documents that need to be presented for licensing;	Regulatory/legislation	VMD to spearhead streamlining of regulatory procedures and licenses at both national and county level
2.	High cost of obtaining compliance certification especially for GMP certificates;	Regulatory/legislation	Make the certificate compliance affordable and practically possible;
3.	High cost of product development and registration	Research, Regulatory/legislation	Regulatory agency to safeguard industry players' investment against counterfeits/fake products; Enforce patent and data protection to recoup investment in research
4.	Lack of infrastructure and human capacity in the development of medicines locally. There is little research on identification of new veterinary medicine molecule locally due to lack of funding. Furthermore, there are very few clinical trials in Kenya	Research	Regulatory bodies, Research intuitions and Veterinary pharmaceutical companies should invest in solution-based research as well as invest in equipment's and personnel training.
5.	Heavy capital investment in machinery	Access to capital/finances	Government to create friendly investment environment and reduce cost of operation; encourage collaboration among players (Public Private Partnerships - PPP)
6.	Delays in clearance of goods at the points of entry	Access to market	Streamline border products regulated by several regulatory bodies e.g. KEBS and VMD where VMD regulated products should be exempted from the KEBS PVOC[37] Scheme. The current Revised PVOC Manual released in October 2018 does not exempt products regulated by VMD. VMD should liaise with KEBS to ensure this is done.
7.	Lack of information on what licenses and certification are required because the regulators (VMD, PCPB and PPB) have not trained them on the requirements or created awareness through ensuring the regulation guidelines are freely available to the public;	Gaps in information flow	Create awareness on Operation licenses and their requirements
8.	Damages and theft of goods on transit;	Trust and ethical issues	Invest in security, tracking systems and trustworthy staff

37 KEBS- Kenya Bureau of Standards (KEBS) and Pre-Export Verification of Conformity (PVoC)

9. Lack of raw materials from local sources and fluctuating availability of quality raw materials from foreign and local sources;	Research	Government to create friendly investment environment and reduce cost of operation; introduce incentives for foreign and local VMP manufacturers.
10. High taxation on raw materials;	Cost of doing business	Lobby for exemption on duty for raw materials
11. Lack of established and credible traceability and monitoring system that will track down individuals and companies bringing in products illegally as this creates unfair advantage for the importers who comply with the law. Furthermore, the illegal products are often counterfeit thus reducing public confidence in veterinary pharmaceutical products;	Trust and image	Regulatory agency to safeguard industry players investment against counterfeits/fake products; stringent laws and fines against illegally smuggled goods; self-regulation of industry players
12. There is no financing services or funding avenues available to aid enterprises engaging in drug importation	Access to capital/finances	Ministry of industrialization to intervene.
13. Delay in product/drug registration- The former regulator had not reviewed new VMP dossier for three years	Regulatory/Legislation	The regulatory to devise methods to hasten the registration process; Application Dossiers to be evaluated on a regular basis e.g. every 2 months. Adopt a performance contract-approach
14. Poor information management – KenTrade has missing VMP imports types and quantities	Gaps in information flows	VMD to contact KenTrade to give them a reporting template for VMP. VMD should also lobby for KenTrade and KRA clearance data to linkages for records and traceability purposes.

3.3.2 Mapping livestock feed millers

A total of 13 millers from Kiambu (6), Nakuru (5) and Kajiado (2) were interviewed. Eleven of the feed millers interviewed produced complete livestock feeds with a monthly average of 559 Metric Tonnes (MT), their production level had a wide range of 12 to 2,400 MT. Two millers were compounding and mixing mineral licks with an average monthly output of 15 to 50 MT. Of the 13 feed millers interviewed, 9 indicated they produced medicated feed. The reason for medicating the feed was to prevent coccidiosis and other diarrhoeal conditions especially in poultry. Four of the nine millers used salinomycin as a coccidiostat while one used robenidine. The other 5 did not indicate what coccidiostat product they used. All nine feed millers sourced coccidiostats from local importing veterinary pharmaceutical companies or large-scale local feed manufacturers. The nine feed millers indicated they sold medicated feeds to multiple customers the main customer mentioned by all nine were poultry farmers, other customers included feed retailers, agrovet retailers and dairy farmers. The validation workshop stakeholders suggested the following questions to be included in future AMU surveys.

- What range of medicated feeds is produced?
- What is the inclusion rate of coccidiostats in feeds?
- Is there a shuttle program in place for coccidiostats?
- What is the total volume of coccidiostats used monthly or annually?
- Do customers have a preference for medicated feeds?

Table 15 below outlines challenges of operation and compliance barriers to set regulations as mentioned by survey respondents and improved by validation workshop participants.

Table 15: Challenges and regulation compliance barriers at feed millers' level

Challenge	Main problem area	Thematic area 1. Regulatory/Legislation 2. Research 3. Trust and image 4. Access to market 5. Access to capital/finances 6. Gaps in information	Possible solution
High cost of compliance	Multiple licensing by KVB, VMD, PCPB, NEMA, KEBS, Public health, County, KEPHIS, NBA	1	VMD to work with other regulatory bodies to review all the legislation and registration requirements to support compliance
Lack of reliable and accessible diagnostic facilities	This limit accurate diagnosis leading to symptomatic treatments Inability to confirm raw material and finished product quality	2, 6	Satellite functional labs/diagnostic facilities close to farmers. Penside diagnostic kits Near Infrared Reflectance spectroscopy (NIR) for real-time feed analysis
Knowledge gaps across the value chain	Quality of training materials, programs, delivery and the trainers Unawareness of the laws and regulations governing the industry	2, 3, 4,6	Practical training programs to all value chain players. The laws and regulations to be prepared and shared widely with the industry. Sensitization and awareness across the value chain Certification courses for relevant industry skills.
Market distortion	Unfair competition from unqualified and or unregistered players/actors Lack of market value for quality outputs Price fluctuations for outputs Credit purchase of farm outputs some not paid Effect of rogue brokers or middlemen	1, 2,4,5,6	Enhanced market surveillance by the regulator/s Partnering with compliant players to eliminate illegal players. Create awareness on quality of farm outputs to the consumers to drive value for quality Encourage value addition to extend shelf-life and increase market value Incentivize processors and aggregators so as to pay for quality and in good time

3.3.3 Mapping veterinary retailers

a. Profile of veterinary retailers

The survey sampled 143 retail outlets, of these, 44 outlets were from Kajiado County and 39 from Nakuru county. Kiambu and Marsabit Counties both had 22 outlets sampled while Nairobi county had 16 outlets included in the survey. One hundred and twenty five retailers (87%) were running agrovet outlets that sold veterinary medicinal products and crop agricultural inputs; 8 (6%) were agrovet/human chemist outlets; 7 (5%) were agrovet and animal feed retailing outlets; 2 were agrovet franchise and 1 was a community disease reporter running a grocery shop that also stocked veterinary medicinal products. The type of professional qualifications for the 143 retailers is shown in table 16 below. Most retailers were animal health certificate holders.

Table 16: Professional qualification of retailers selling veterinary medicinal products

Level of Education	Frequency	Percent
Animal Health Certificate	68	48%
Diploma in Animal Health	28	20%
Secondary education	16	11%
Other unrelated qualification	12	8%
Bachelor of Veterinary Medicine	7	5%
Other animal health related degree	6	4%
Primary education	5	3%
No formal education	1	1%
Total	**143**	

Figure 7 below highlights the percentage distribution of VMP retailers' source of medicated animal feeds and their main customer base.

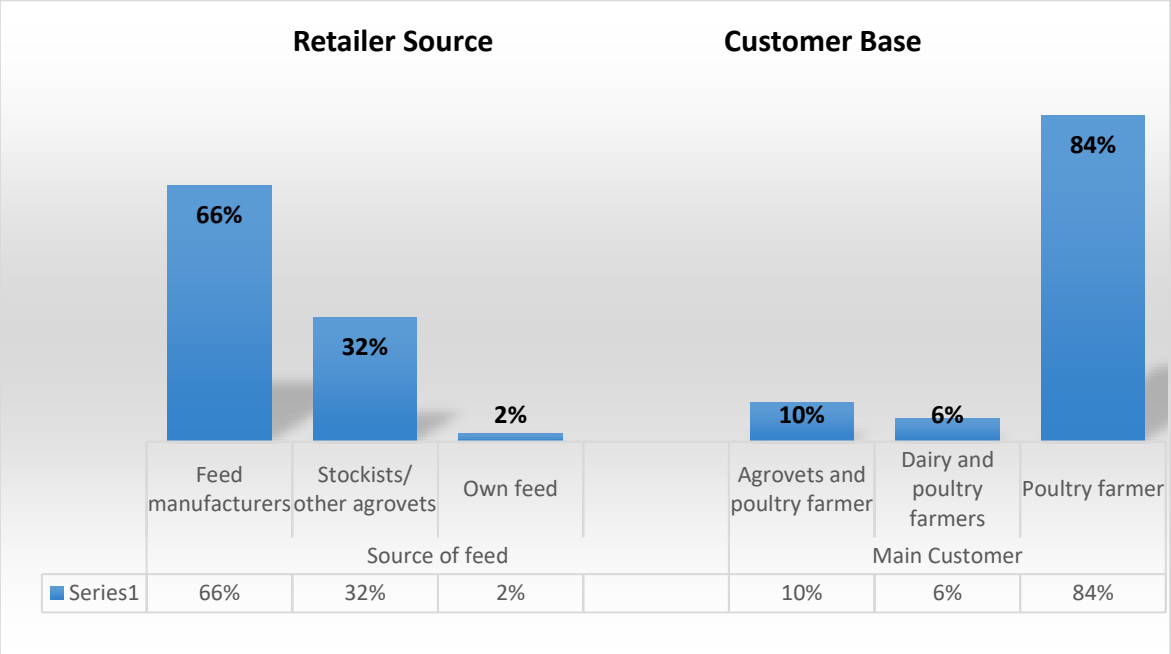


Figure 7: Veterinary retailers' source of medicated livestock feeds and customer base

b. Monthly quantities of antibiotic sales at retailers' level

The baseline survey targeted collection of monthly sales for antibiotic products only. The survey design did not capture other VMP categories of interest. The total monthly quantity of antibiotics sold at retailer level was 1710 Kgs (Table 17).

Table 17: Monthly quantity of antibiotic sales at retailer level by class and route of administration

Antibiotic class (AI)	QUANTITY (KGS)					
	Parenteral	Oral powder	Boluses & Pessaries	Topical Spray	Intramammary (IMM)	Total
Tetracyclines	311.84	228.51	0.56	13.86	0	**554.77**
Sulfonamides	20.28	178.24	39.09	0	0.30	**237.91**
Aminoglycosides	171.37	7.28	0	0	2.13	**180.78**
Penicillins	160.20	3	0	0	6.86	**170.06**
Amprolium& Toltrazuril	0	138.94	0	0	0	**138.94**
Other antibiotic - colistin	0	132.09	0	0	0	**132.09**
Recent molecule- fosfomycin& radamycin	0	123.83	0	0	0	**123.83**
Macrolides	47.67	42.28	0	0	0.01	**89.96**
Trimethoprim	3.98	39.36	2.15	0	0.07	**45.56**
Fluoroquinoloes	26.43	0	0	0	0	**26.43**
Cephalosporin	8.04	0	0	0	0.51	**8.55**
Thiamphenicol	0.70	0	0	0	0	**0.7**
TOTAL	**750.50**	**893.53**	**41.8**	**13.86**	**9.88**	**1709.57**

Tetracycline were the highest sold antibiotic class with sale quantities of 554.77 Kgs per month, it also had the highest quantities sold in its parenteral form (311.84 kgs), oral form (228.51 kgs) and topical (13.86 Kgs). Other parenteral antibiotic classes with quantity sales of more than 100 Kgs were Aminoglycosides (171.37Kgs) and Penicillins (160.20 Kgs). Antibiotic classes with quantity sales of less than 10 Kgs were Cephalosporins (8.04 kgs), Trimethoprim (3.98 kgs) and Thiamphenicol (0.70 Kgs). The most common oral bolus and intrauterine pessaries preparation were from the Sulfonamides class of antibiotic with quantity sales of 39.09 Kgs.

The survey sought to find out the quantities in kilogrammes of active ingredient of parenteral antibiotics sold in each county (Table 18) below. The 143 survey retailers mainly sold 9 classes of parenteral antibiotics. Generally, tetracycline recorded the highest quantity (311.84 kg) sold across all the counties while aminoglycosides recorded the second highest sales (171.37 kg) in all the counties. Kajiado County had the highest monthly sales (330.64 Kgs) of almost all quantities of parenteral antibiotics with the highest being tetracycline at 141.40 Kgs. Kajiado also had the highest number (44) of VMP retailers sampled. Thiamphenicol was only sold in Kajiado County and recorded zero quantity sold in all other counties. Marsabit County recorded the second largest sales of almost all parenteral classes of antibiotics sold while Kiambu had the highest consumption of Sulfonamides (9.88 kg).

Table 18: Monthly quantity of parenteral antibiotic sales at retailer level by County

Parenteral antibiotic Quantity (Kgs)	Kajiado (n=44)	Marsabit (n=22)	Kiambu (n=22)	Nakuru (n=39)	Nairobi (n=16)	Total (n=143)
Penicillins	53.87	24.99	28.95	26.32	26.07	**160.20**
Aminoglycosides	72.83	19.38	30.53	25.98	22.66	**171.37**
Cephalosporins	8.00	-	-	0.01	0.03	**8.04**
Fluoroquinolones	22.19	-	2.92	0.53	0.79	**26.43**
Macrolides	27.80	4.87	4.02	3.60	7.38	**47.67**
Sulfonamides	3.28	0.60	9.88	4.04	2.48	**20.28**
Trimethoprim	0.58	0.12	1.98	0.81	0.50	**3.98**
Thiamphenicol	0.70	-	-	-	-	**0.70**
Tetracyclines	141.40	63.68	32.89	41.70	32.16	**311.84**
Total	**330.64**	**113.64**	**111.17**	**102.98**	**92.06**	**750.50**

Only 107 of the 143 retailers' responses were recorded for the question that sought to know the main VMP supplier. As shown in figure 8 below, about half (55;51%) of the

retailers purchased antibiotics supplies exclusively from pharmaceutical companies, 34 (32%) indicated they purchased from other agrovets, 11 (10%) from both pharmaceutical companies and other agrovets and 7 (7%) from wholesale distributor companies.

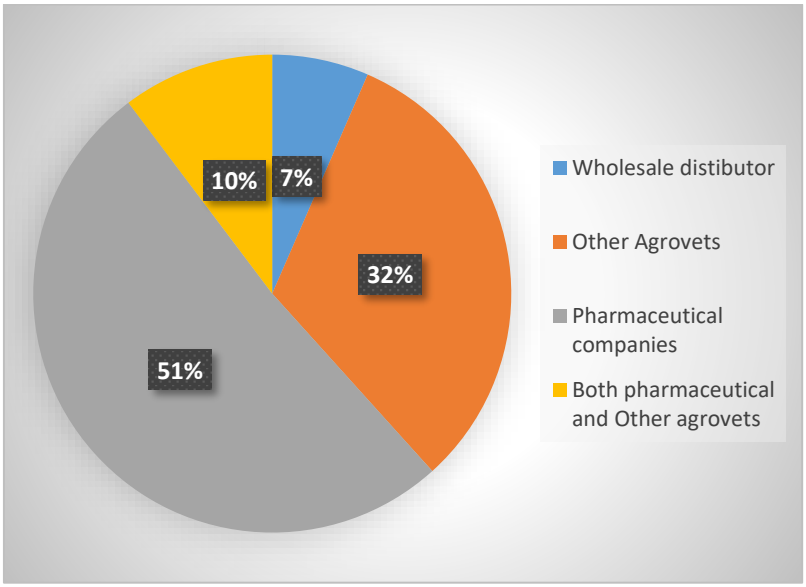


Figure 8: Main source of veterinary antibiotics supplies for agrovet retailers

Similarly, only 100 out of the 143 retailers responses were recorded for the question that wanted to know who purchased parenteral antibiotics from retailers. The retailers indicated that animal health practitioners (65) with or without clinics were their main customers. Other customers were livestock keepers (27) from pastoralist production systems and farmers (8) from intensive production systems.

c. Retailers Knowledge, Attitude and Practices on AMR and AMU

The survey assessed the retailer's knowledge on Antimicrobial Resistance (AMR) by having the 143 survey respondents define AMR. Close to half (46%) of the respondents were knowledgeable about AMR with 66 retailers defining it as when bacteria are resistant to antibiotics. However, 33 (23%) thought that AMR was a term used for misuse of antibiotics and 44 indicated they did not know what AMR was with one of the 44 retailers thinking it was a form of a livestock disease (Figure 9).

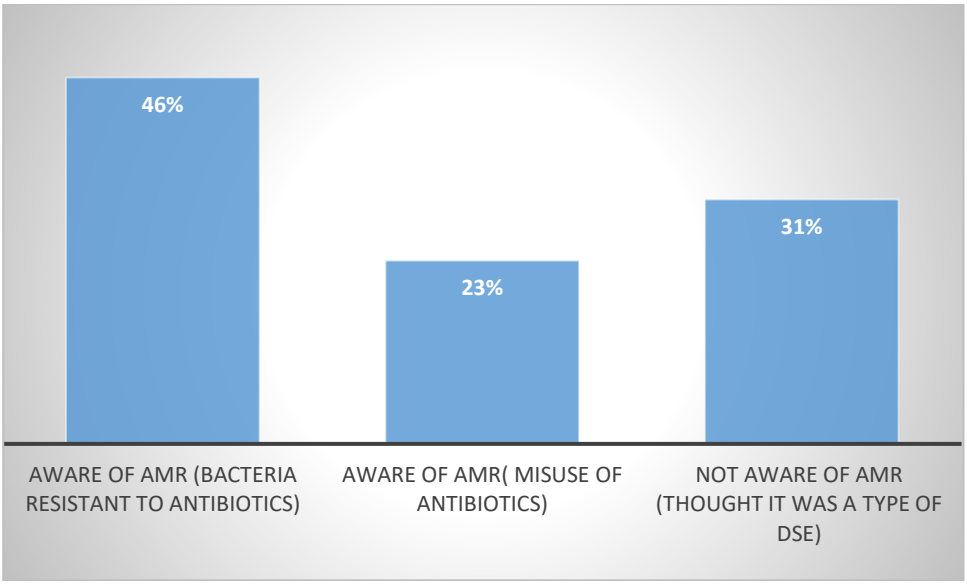


Figure 9: Retailers Knowledge on Antimicrobial Resistance

The priority factors considered when choosing antibiotic were assessed and are presented in table 19 below. Most retailers considered efficacy of the drug as the most important factor when advising the client to purchase the drug.

Table 19. Factors that determine choice of antibiotic drug sold by retailers

Factor	Most important factor	
	Frequency	Percent
Efficacy	65	46%
Recommended by Vet or AHA*	37	26%
Customer preference	20	14%
Price	14	10%
Availability	6	4%
Total	**142**	**100**

*Animal Health Assistant

In general, retailers indicated they mostly dispensed veterinary medicinal products to treat the following livestock diseases as listed in table 20 below.

Table 20: List of top five diseases managed at retailers' level

Multiple response set (n=592)		
Type of livestock disease	**FREQUENCY**	**PERCENTAGE**
Poultry-viral diseases (fowl pox; NCD; IB; IBD)	60	10
Poultry-bacterial diseases (CRD; fowl cholera; infectious coryza)	49	8

Multiple response set (n=592)		
Type of livestock disease	**FREQUENCY**	**PERCENTAGE**
Poultry-zoonotic (Collibacillosis; Salmonellosis)	23	4
Poultry-parasitic (coccidiosis)	55	9
Ruminant-respiratory signs (Pneumoniae; coughing)	59	10
Ruminant-git signs (helminthiasis; diarrhoea)	47	8
Ruminant-skin; udder; uterus (mastitis; wounds)	64	11
Ruminant-TBD (Anaplasma; ECF; heart water; Babesia)	97	16
Ruminant-notifiable (FMD; CCPP; CBPP; SGP; LSD; PPR; anthrax; BQ)	138	23
TOTAL	**592**	**100**

Key: (NCD-New Castle Disease; IB-Infectious Bronchitis; IBD-Infectious Bursal Disease (Gumboro); ECF-East Coast Fever; FMD-Foot and Mouth Disease; CCPP-Contagious Caprine PleuroPneumoniae; Contagious Bovine Pleuro Pneumoniae; SGP-Sheep and Goat Pox; LSD-Lumpy Skin Disease; PPR-Peste des Petits Ruminants; BQ-Black Quarter)

The two main barriers to compliance mentioned by respondents were the high cost incurred to purchase relevant licences and inspection services. They requested the regulator VMD to spearhead streamlining of registration and licensing requirements at national and county level. The lack of prosecution of illegal retailers due to limited financial and human capacity for regulation by the Kenya Veterinary Board and VMD was the second main challenge that hindered compliance. Retailers suggested the following ways to enhance compliance these included; Awareness creation; farmer training; reducing cost of compliance; punishing quacks and enforcement of existing laws and regulations.

3.3.4 Mapping Animal Health Private Practitioners

The study sampled 45 private animal health practitioners from 5 counties of Kajiado (13), Nairobi (11), Nakuru (10), Kiambu (10) and Marsabit (1). Kajiado had the highest proportion of private practitioners surveyed while Marsabit had only one private practitioner sampled. Due to the small county level sample size and the fact that this data set had missing information the results are presented as aggregation for all counties as detailed below.

a. Profile of private animal health practitioners

The overall average age of practitioners surveyed for all counties was 34 years with a wide range of 25 to 52 years. Only 29 private practitioners from all counties sampled were female with majority (71) being male. More than half that is 24 (53%) of the 45 respondents surveyed indicated they were holders of animal health certificates (Figure 10). The 45 private practitioners had the following business enterprises; 22 (49%) offered freelance animal health services and had no premises of operation,13 (29%)

offered animal health services from their agrovet enterprises and 5 (11%) offered services either from an agrovet or established clinic premises (Figure 11). The main client base handled by all 45 private practitioners included 18 (40%) from semi-intensive livestock production system, 15 (33%) from the extensive pastoralist system and 12 (27%) from the intensive system.

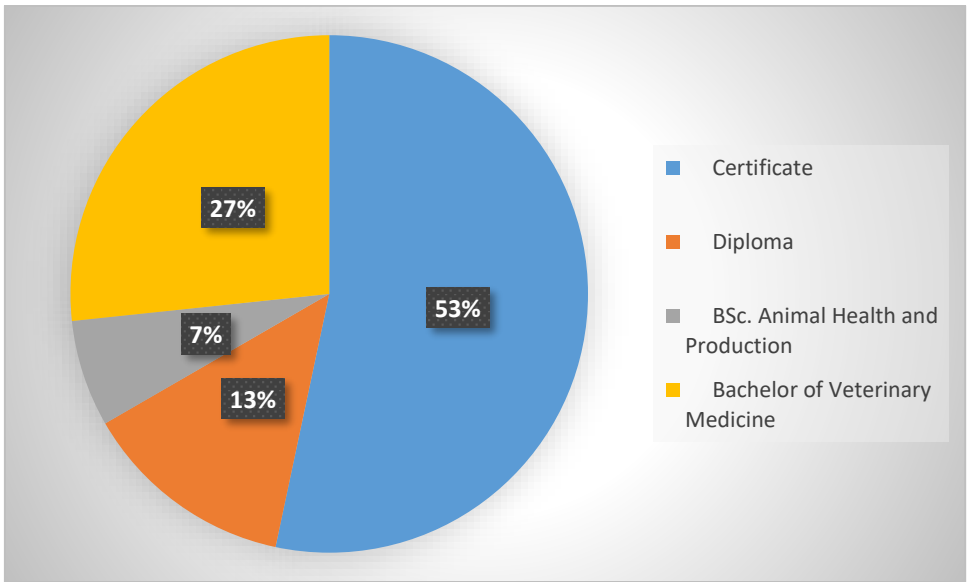


Figure 10: Professional qualification profile of private animal health practioners

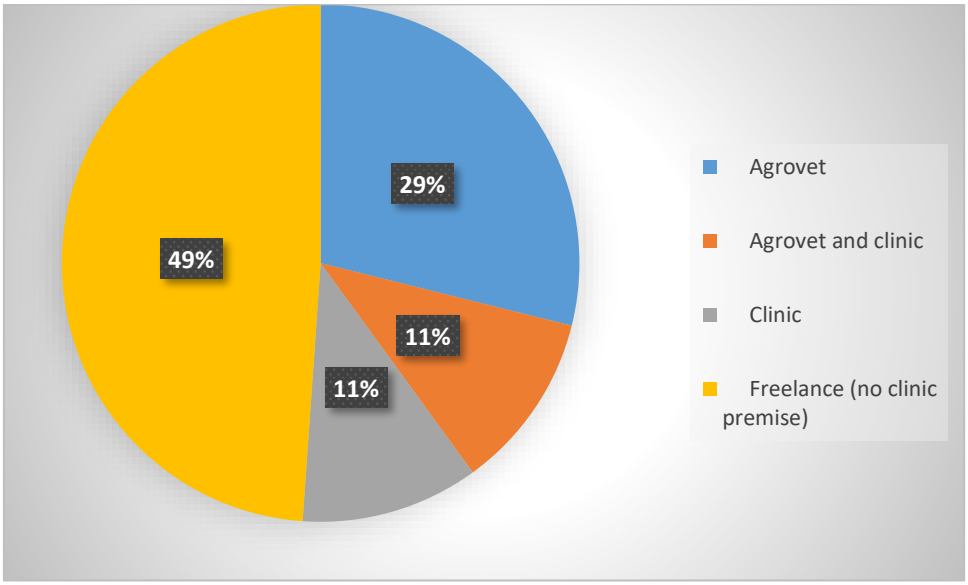


Figure 11: Type of private animal health service provision enterprise

b. Monthly quantities of Veterinary Medicines use at private practitioners' level

The main Veterinary Medicinal Product (VMP) used by all 45 practitioners that had quantities of greater than 1 kg per month were tetracyclines (17 Kgs), Sulfonamides (14

Kgs), benzimidazoles (7 Kgs), penicillins (4 Kgs), macrolides (3 Kgs) and aminoglycosides (3 Kgs) as shown in figure 12 below. In general, the 45 practitioners managed the following conditions as shown in figure 13 below. The percentage calculation is from 139 responses given by the 45 private practitioners. Tick borne diseases such as ECF, Anaplasmosis and Babesiosis were the main infections seen in cattle while Contagious Caprine Pleuropneumoniae (CCPP) was the main disease seen in goats. The main poultry diseases encountered by private practitioners' level included coccidiosis, Infectious Coryza and Chronic Respiratory Disease (CRD).

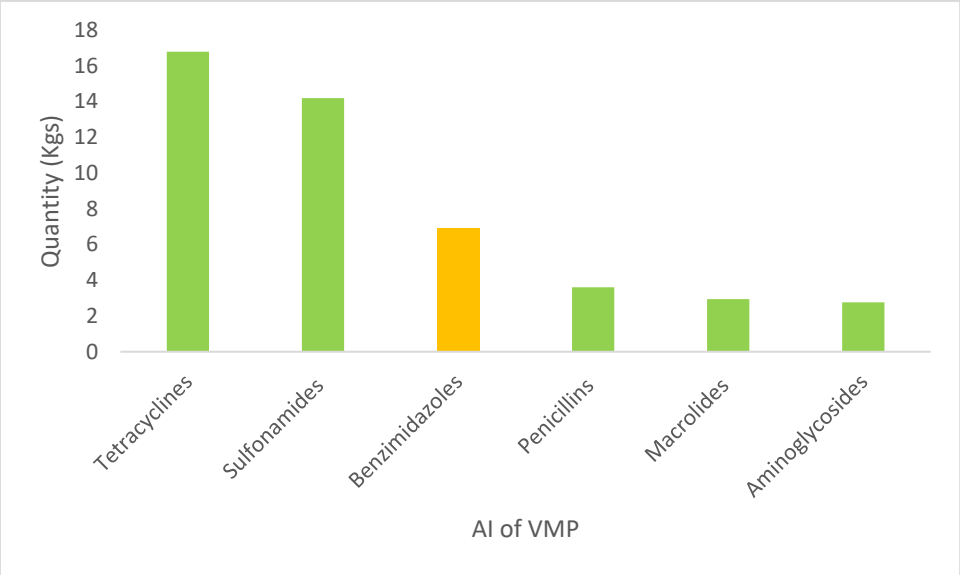


Figure 12: Monthly of VMP use at private practitioners' level

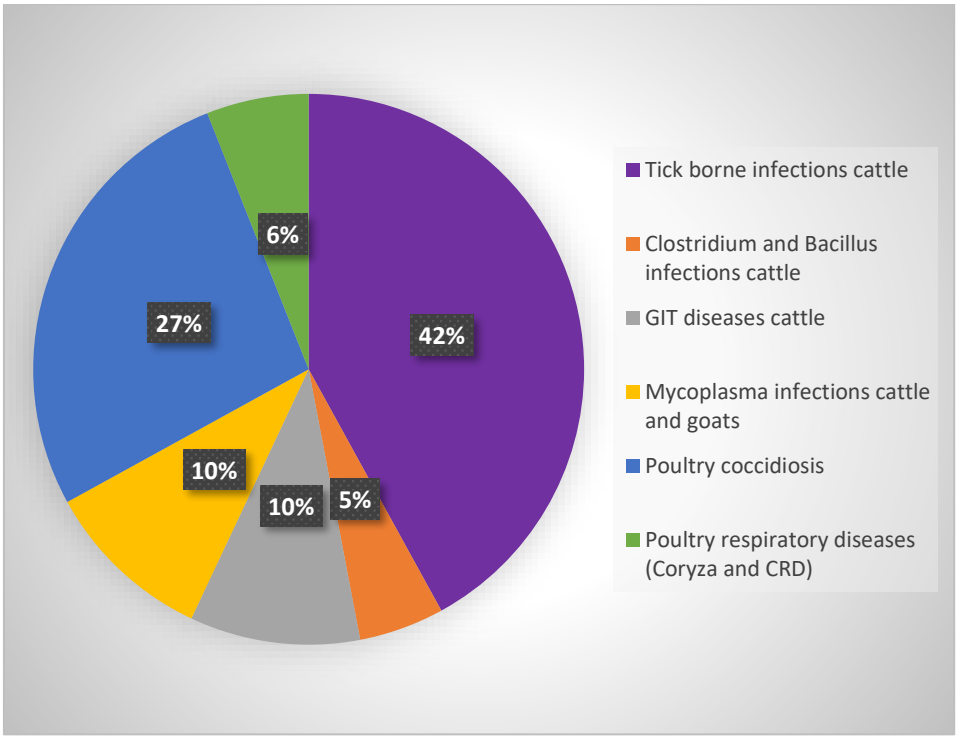


Figure 13: Types of livestock diseases managed by private animal health practitioners

c. Private practitioners Knowledge, Attitude and Practices on AMR and AMU

Table 10 below summarises AMU and AMR knowledge and practice as well as the main challenges hindering successful treatment of conditions and adherence to set regulations by private animal health practitioners. AMR was considered by 30 of the 45 practitioners as a very serious problem. Only 2 of the 45 indicated that AMR was not a serious problem. Most (38) of the practitioners used clinical diagnosis to arrive at treatment protocols (AMU) while 7 combined clinical diagnosis with laboratory testing. The private practitioners indicated they sourced VMP products from multiple sources, a total of 84 responses were recorded, most of the 45 practitioners obtained their antimicrobials products from agrovets (35) and drug pharmaceutical sales representatives (31). The 45 practitioners disposed expired and unused drugs in pit latrines (16), others buried (8) them while 6 returned them to the supplier. Burning was also mentioned by 6 of the practitioners.

Table 21: Private practitioners Knowledge, Attitude and Practices on AMR and AMU

Variable		Frequency (n=45)	Percentage (%)
How do you arrive at diagnosis?			
clinical signs		38	84%
clinical signs & laboratory tests		7	16%
Where do you VMP?	**n=84**		
Agrovets		35	78%

Variable	Frequency (n=45)	Percentage (%)
Pharmaceutical sales representatives	31	69%
Chemists	11	24%
Fellow vets/paravets	3	7%
Franchise agrovet	4	9%
How do you dispose unused or expired medicines?		
Pit latrines	16	36%
Bury them	8	18%
Returned to VMP supplier	6	14%
Burning	6	13%
Rubbish pit	5	11%
Don't dispose use them	3	7%
Main challenges in achieving treatment success		
Late reporting by farmers	19	42%
Lack of confirmatory laboratory diagnosis	8	18%
Drug resistance	7	16%
Prevalence of quacks	7	16%
Farmers treat animals by themselves	4	9%
Severity of AMR problem		
Very serious	30	66%
Do not Know what AMR is	13	30%
Not a serious problem	2	5%
Main barrier to statutory compliance		
Ignorance	12	27
failure by KVB to deal with quacks	13	28
Unrestricted access of drugs by farmers	20	44

The stakeholder's validation workshop participants were able to identify additional information on barriers to statutory compliance as well as proposes possible solutions. This information is summarised in table 22 below.

Table 22: Barriers to statutory compliance and proposed solutions

Challenge	Main problem area	Thematic area 1. Regulatory/Legislation 2. Research 3. Trust and image 4. Access to market 5. Access to capital/finances 6. Gaps in information 7. High transaction cost	Possible solution
Ignorance	Most VMP actors are ignorant of VSVP Act, VMD regulation with respect licensing, inspections & registration	6	Awareness & communication by KVB, VMD, KVA, Associations for paraprofessionals are key as AHA form the bulk of veterinary retailers and private practitioners.

Challenge	Main problem area	Thematic area 1. Regulatory/Legislation 2. Research 3. Trust and image 4. Access to market 5. Access to capital/finances 6. Gaps in information 7. High transaction cost	Possible solution
Failure by KVB to deal with quacks	Lack of enforcement of VSVP Act and VMD regulation	1	• Outsource/delegate enforcement by appointing county-based inspectors • Identify and prosecute quacks • Decentralize registration
Unrestricted access of drugs by farmers	Lack of regulation to make VMP especially antibiotics to be prescription only medication and not Over the Counter medicine	1, 4, 7	• VMD to spear head enforcement VSVP Act and if necessary, draw up VMP use guidelines/formulary
High cost of compliance with multiple registration and licensing	Multiple licenses at county and national level	5, 7	• VMD to spear head review of licenses at both county and national level to ease the cost of doing business and avoid double taxation • Linking practitioners to credit providers
Lack of relevant skill update (on AMU & AMR)	CPD have been commercialized and don't respond to industry needs	1, 2, 6	• KVB to spearhead structuring of CPD to meet the skill gaps and propose areas that require training so as to update practitioners on current and emerging issues

3.3.5 Mapping veterinary medicinal products use at farmer level

a. Farmers profile

A total of 139 farmers from 4 counties (Marsabit (55); Kajiado (54), Nakuru (14) and Kiambu (13) participated in the survey. The mean age of the 139 survey participants was 45 years (SD13) with a wide range of between 20 and 85 years The level of formal education varied with 37 (27%) indicating they had primary education, 36 (26%) had no formal education and only 5 (4%) had university education (Figure 14).

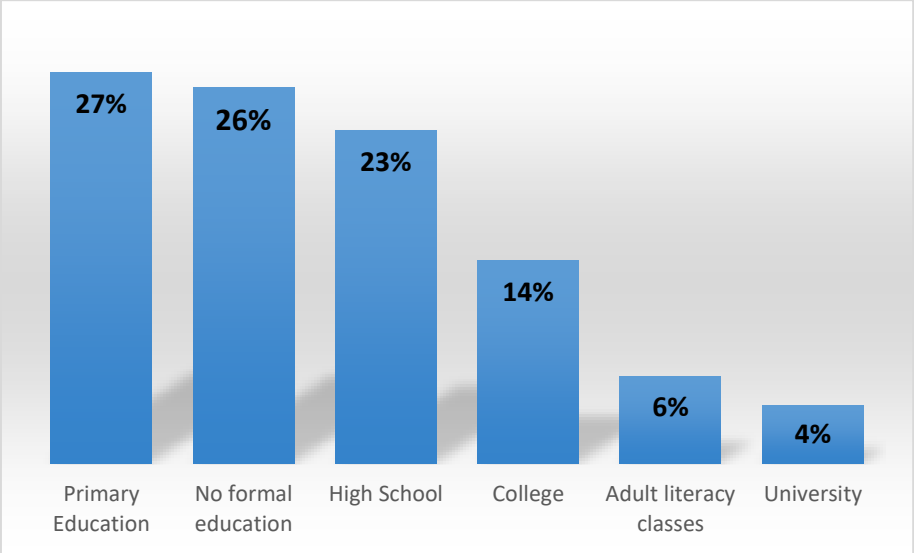
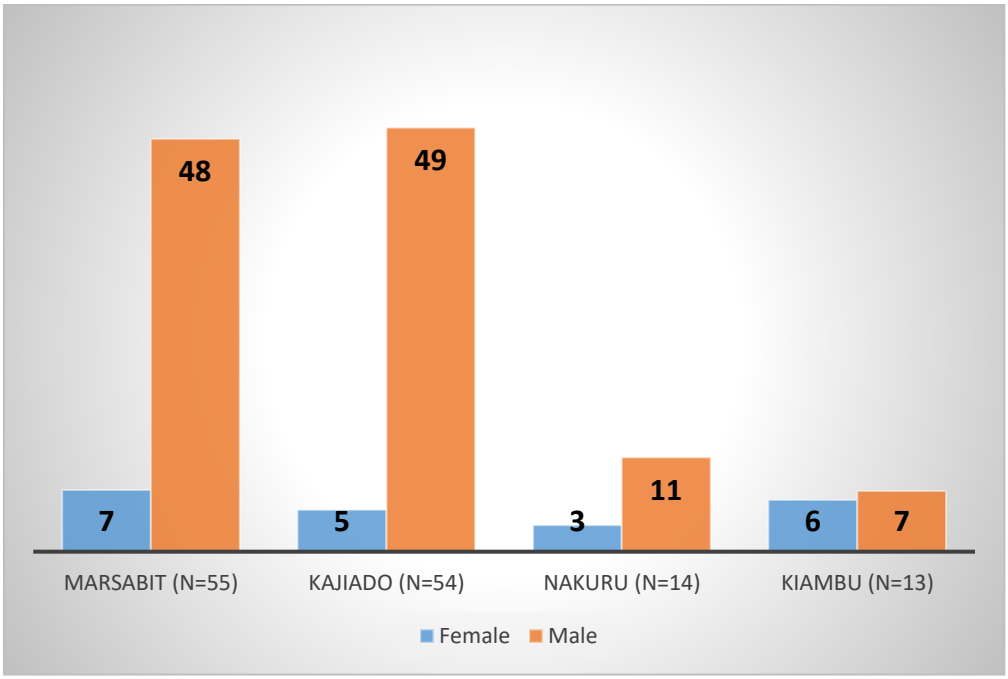


Figure 14: Overall level of survey farmers level of formal education

Majority (115) of farmers interviewed were male. (Figure 15).



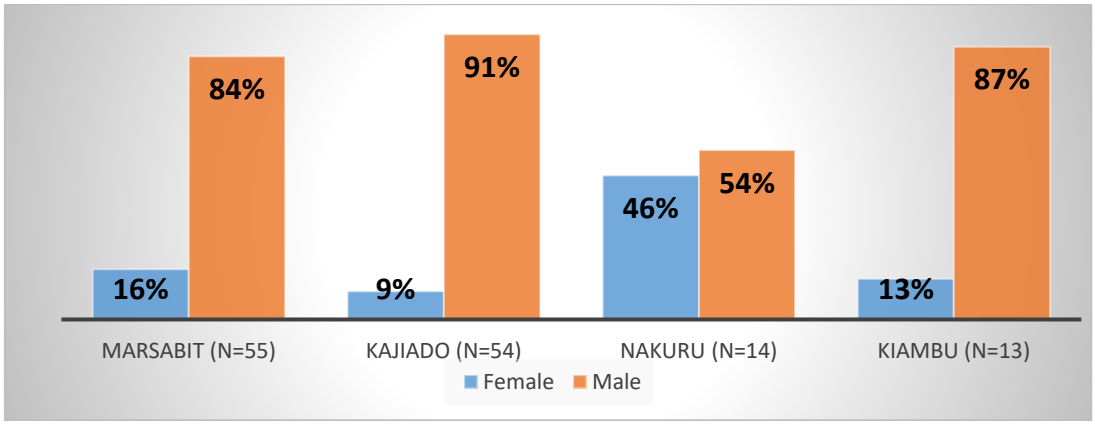


Figure 15:Gender distribution by county of farmers surveyed

Three categories of livestock production systems were sampled extensive, intensive, and semi-intensive. The overall results show that extensive management system was the most sampled as reported by 95 (68%) of the 139 respondents. Kiambu and Nakuru Counties had majority of farmers practicing intensive livestock keeping (Table 23). The main livestock species kept by respondents were small ruminant (81%) and beef cattle (73%) this may be because Marsabit and Kajiado had the largest sample size of farmers surveyed. Marsabit and Kajiado are classified as extensive livestock production systems that predominately keep small ruminants and beef cattle. Local chicken (26%), dairy cattle (24%) and camel (15%) were other livestock species kept (Table 24). Most farmers in Kiambu and Nakuru Counties indicated that dairy farming was the main livelihood enterprise. Nakuru County reported the highest (42%) percentage of respondents rearing local-chicken breeds ('Kienyeji').

Table 23: Type of Livestock production system by county

Variable	All (%) n=139	Kajiado (%) n=54	Kiambu (%) n=13	Marsabit (%) n=55	Nakuru (%) n=14
Management system					
Extensive	68	63	-	100	21
Intensive	16	4	92	-	57
Semi-intensive	17	33	8	-	21

Table 24: Type of livestock species kept be farmers by county

Farmers' enterprise	All (%) n=139	Kajiado (%) n=54	Kiambu (%) n=13	Marsabit (%) n=55	Nakuru (%) n=14
Beef cattle	73	89	-	85	28
Camels	15	4	-	35	-
Dairy cattle	24	20	77	-	79
Small ruminants	81	87	23	95	50
Local chicken	26	33	15	14	42

b. Monthly quantity of veterinary medicinal product use at farmer level

Overall, the 139 farmers surveyed used a monthly total of 23.67 Kgs of tetracyclines and 9.36 Kgs of Penicillins (Table 25). The main anthelmintic compound used was Benzimidazoles at 8.3 kgs per month. Cephalosporins antibiotics were the least consumed drug at 0.002 kg per month.

Table 25: Monthly quantity of veterinary medicinal product used by livestock keepers

Antimicrobial API	Monthly quantity (Kg)
Tetracyclines	23.666
Penicillins	9.359
Aminoglycoside- dihydrostreptomycin	8.296
Benzimidazoles- albendazole	4.035
Macrolides - Tylosin	3.147
Homidium chloride- Novidium®	0.046
Imidazothiazoles- Levamisole	0.165
Buparvaquone	0.054
Salicylanilide-Closantel	0.467
Sulfonamides	0.403
Trimethoprim	0.041
Macrocyclic lactones- Ivermectin	0.037
Diminazene aceturate- Berenil®	0.075
Cephalosporins	0.002
Quinapyramine salts	0.023
Aminoglycoside- Gentamycin	0.045

The farmers listed the following livestock diseases as causing the largest economic loss;

- In goats- CCPP
- In cattle- ECF, FMD and LSD in cattle
- In camels - Trypanosomiasis

c. Farmers Knowledge, Attitude and Practices on AMU

Respondents (n=139) were asked how they diagnosed sick animals. Majority (111) mentioned identification of characteristic clinical signs associated with the disease. A few (15) relied on both clinical signs and laboratory tests results following sample collection and submission by animal health practitioners. Interestingly, 13 of respondents cited guesswork as their method of identifying diseases in sick animals. Of the 139 respondents, less than half (44) indicated they obtained drug prescription from animal health service providers. The two main sources of antibiotics identified by 139 livestock keepers included, mainly agrovet stores or agrovet franchise (124), veterinary pharmaceutical companies' sales representatives (15). With regard to disposal of expired/unused drugs, 87 (63%) of livestock keepers used pit latrines to dispose drugs, 30 (22%) buried the

expired/unused drugs and 21 (15 %) disposed drugs in open fields. Farmers identified the following factors as reasons that caused treatment failure;

- Improper dosage and misuse of drugs was the main reason given by 39% (54) of respondents;
- 27% (38) of respondents cited misdiagnosis;
- Poo drug quality was cited by 18% (25) of respondents;
- Shortage of animal health service providers was cited by 16% (22).

Livestock keepers proposed several interventions to help in the regulation and proper treatment of livestock, 53% (74) of the farmers suggested that county governments should employ more veterinary service providers, creation of awareness was suggested by 33% (46) of respondents while 14% (19) of respondents proposed that county governments should ensure provision of quality drugs and proper regulation of veterinary drugs by relevant authorities.

3.4 Antimicrobial Use (AMU) Surveillance Tool

The validation workshop participants noted that based on the survey findings the VMP import (KenTrade) and sales data at wholesale and retail levels were the most reliable data sets that can be used to track AMU trends in food animals. VMD was urged before piloting the AMU tool to ensure that they spearhead streamlining of import data for example, the market authorization certificate that is given after review of a new VMP product dossier and approval does not specify the VMP product strength and recommended packaging sizes. This has resulted in the gap seen in the Import Declaration Form (IDF) and KenTrade data. VMD should ensure that each IDF clearly stipulates the VMP AI, concentration strength and packaging sizes. In addition, VMD should advocate for integration of KenTrade and KRA data sets to be able to track actual VMP imports. VMD informed validation workshop participants that it had already made it a legislative requirement for retailers to report sales data on what they get and what they dispense. Participants noted that if this was to be implemented and accepted, VMD needed to ensure the AMU tool is simple and digitalised and hosted as a mobile application accessible by SMS, smart phone application or desktop. The tool should have relevant short, prefilled questions with functionality to allow back end calculation of AI quantity in Kgs to avoid entry errors. The period of reporting should be monthly for all VMP supply chain levels but for KENTRDE quarterly. VMD should consider field data collection in sentinel surveillance sites identified as high-risk exit and entry points of illegal or counterfeit VMP. The data sources proposed by the validation workshop are listed below;

- VMP Import data should be from VMD, KENTRADE, KRA, Large scale livestock Production farms like KWS, Kenchic, Farmers choice;

- VMP export data from VMD, importing companies, wholesale distributors and relevant government institutions;
- VMP sales data from veterinary VMP wholesalers and retailers;
- VMP use data at practitioners and famers level that should include data of livestock numbers if possible;

Discussion

Suitability of study design

The use of a country's veterinary medicinal products imports and sales data has been shown to be an effective starting point to quantify Antimicrobial Use (AMU) in food animals[38]. The main rationale for collecting data on antimicrobials used in a country or region is based on scientific evidence that links the indiscriminate AMU in humans and animals with increased risk of hastening the natural process by which microbes become resistant to antimicrobial agents[39,40]. AMU surveillance and trend monitoring are widely acknowledged as critical components in the response of Antimicrobial resistance (AMR) as well as being effective strategies to quantify the risk of developing and spreading antibiotic resistance in the food-chains[41].

The measurement of AMU in human and animal health and production system is a central goal of the Global Action Plan on Antimicrobial Resistance and the complementary plans and strategies developed by the Food and Agriculture Organization of the United Nations (FAO-UN), World Organization for Animal Health (OIE) and country specific AMR containment National Action Plans[42]. However, many Low- and Middle-Income countries (LMICs) lack or have weak systems for collecting and analysing data on AMR and AMU as they lack resources, have weak laboratory infrastructure and few trained personnel. In, addition, the high prevalence of counterfeit and substandard antimicrobials and diagnostics further complicate the situation[43]. This challenge will be further exacerbated by the projections that LMICs will increase the use of antimicrobial in food animal production sectors so as to expand intensive production systems that will meet the

38 European Medicines Agency, 2011. 'Trends in the sales of veterinary antimicrobial agents in nine European countries (2005-2009)' (EMA/238630/2011).

39 James A. Ayukekbong, Michel Ntemgwa and Andrew N. Atabe (2017). The threat of antimicrobial resistance in developing countries: causes and control strategies. Antimicrobial Resistance and Infection Control 6:47. https://doi.org/10.1186/s13756-017-0208-x

40 OIE annual report on the use of antimicrobial agents in animals. Better understanding of the global situation (2016). Accessed from http://www.oie.int/scientific-expertise/veterinary-products/antimicrobials/

41 Spellberg, B. 2011. The antibiotic crisis: Can we reverse 65 years of failed stewardship? Archives of Internal Medicine 171(12):1080–1081.

42 Schar D, Sommanustweechai A, Laxminarayan R, Tangcharoensathien V (2018). Surveillance of antimicrobial consumption in animal production sectors of low- and middle-income countries: Optimizing use and addressing antimicrobial resistance. PLoS Med 15(3):e1002521. https://doi.org/10.1371/journal.pmed.1002521

43Global Antibiotic Resistance Partnership—Kenya Working Group. 2011. Situation Analysis and Recommendations: Antibiotic Use and Resistance in Kenya. Washington, DC and New Delhi: Center for Disease Dynamics, Economics & Policy.

rapidly increasing demand for animal-source nutrition[44]. The OIE template used by countries to self-report AMU in animals encourages countries to report all antimicrobial classes except ionophores used in animals whether they are used for therapeutic use, prevention of disease, growth promotion or indicated for humans but used in animals. The OIE form requests member states to report the aggregated quantity of antimicrobial active ingredient used in animals in kilograms (kgs)[45,46]. In addition, OIE understands the challenges faced by LMICs and allows phased reporting starting with AMU volumes derived from import and sales data, followed by species reporting and then finally actual antimicrobial use in livestock at farmer level. The study design used in the baseline study that aimed at mapping the 2017 veterinary medicinal product supply chain in Kenya was therefore an ideal starting point that will guide the new regulatory agency in Kenya, the Veterinary Medicine Directorate (VMD) better understand the type and quantity of target VMP imports sold and distributed in the country so as to better carry out its registration, licensing, pharmacovigilance and post market surveillance mandates. However, the study design, sampling and lack of harmonization of the data collection questionnaire tool resulted in data that could not be compared across the VMP supply chain. The study revealed that the import data from KenTrade when integrated with the PCPB data from KRA customs was a more robust data set that was able to give a good representation of actual acaricide and pyrethroids imports into the country. VMD should ensure future survey studies use a harmonized data collection tool to ensure similar information is collected at each VMP supply chain level. In addition, VMD should give guidelines and where necessary change documents that capture VMP imports by ensuring that all licensing documents such as Import Declaration Form (IDF), export permit and certificate of registration (Marketing Authorization) of new VMP products detail clearly for each product the Active Pharmaceutical Ingredient (API), the different preparation strengths using OIE guidelines on metric measures and product packaging sizes and quantities. These guidelines should be shared with KenTrade and KRA customs. VMD should also lobby for linkage of its data base with KenTrade and KRA customs. This will allow VMD to better track import and export VMP in the country.

44 The FAO action plan on antimicrobial resistance 2016-2020

45 http://www.oie.int/scientific-expertise/veterinary-products/antimicrobials/

46 The OIE International Committee unanimously adopted the List of Antimicrobial Agents of Veterinary Importance at its 75th General Session in May 2007 (Resolution No. XXVIII). Accessed from https://www.oie.int/doc/ged/D9840.PDF

Target Veterinary Medicinal Products

The choice of VMP that is antibiotics, anthelmintics, ectoparasiticides and antiprotozoal included in the study was informed by scientific and anecdotal evidence that have linked their use to increased resistance patterns in Kenya[47,48,49].

Acaricide and Pyrethroids resistance

Ectoparasiticides continue to be the primary means of control for arthropod ectoparasite in livestock. Intensive use of these products has led to emergence of resistance to organochlorines, organophosphates and pyrethroids especially in fleas. The underlying process of arthropod resistance is based on genetic selection which is a natural evolutionary process that is hastened by the high degree of application. It is estimated that over 500 arthropod species are known to be resistant to one or more ectoparasiticides. However, the good news is that only 3 % of the 500 species are of veterinary importance[50,51]. To safeguard the current effectiveness of these chemicals strategies that prolong their effectiveness and reduce their environmental impact are needed. The current strategies should be based on integrated pest management (IPM) techniques, which exploits the biology of the arthropods being controlled and reduces pesticide use, hence conserving the environment. IPM aims at using minimal pesticides so as to suppress the pest populations below the economic injury level (EIL)[52]. Analysis of the 2017 KenTrade import requests revealed that only three ectoparasiticides were imported these were organophosphate, amitraz and pyrethroids. However, after the validation workshop

47 Gitau, G.K., Bundi, R.M.,Vanleeuwen, J. & Mulei,C.M., 2014, 'Mastitogenic bacteria isolated from dairy cows in Kenya and their antimicrobial sensitivity',Journal of the South African Veterinary association 85(1). Available from https://profiles.uonbi.ac.ke/cmulei/files/mulei_c_2014_mastitogenic_bacteria_isolated_from_dairy_cows_in_kenya.pdf

48 Waruiru, R.M., Maingi, N., Gichanga EJ. "Prevalence of anthelmintic resistance in sheep in three districts of Kenya.". In: The Annual Scientific Conference of the Faculty of Veterinary Medicine, University of Nairobi. Nairobi, Kenya; 1990 and https://www.sciencedirect.com/science/article/pii/S0304401797001957

49 Chitanga S, Marcotty T, Namangala B, Van den Bossche P, Van Den Abbeele J, et al. (2011) High Prevalence of Drug Resistance in Animal Trypanosomes without a History of Drug Exposure. PLOS Neglected Tropical Diseases 5(12): e1454. https://doi.org/10.1371/journal.pntd.0001454

50 Vudriko P, Okwee-Acai J, Tayebwa DS, et al. Emergence of multi-acaricide resistant Rhipicephalus ticks and its implication on chemical tick control in Uganda. Parasit Vectors. 2016;9:4. Published 2016 Jan 4. doi:10.1186/s13071-015-1278-3. Available from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4700616/

51 Kunz S.E and Kemp D H. (1994). Insecticides and acaricides :resistance and environmental impact. Rev. sci. tech. Off. int. Epiz., 1994,13 (4), 1249-1286 https://www.oie.int/doc/ged/D8943.PDF

52 Vudriko P, Okwee-Acai J, Tayebwa DS, et al. Emergence of multi-acaricide resistant Rhipicephalus ticks and its implication on chemical tick control in Uganda. Parasit Vectors. 2016;9:4. Published 2016 Jan 4. doi:10.1186/s13071-015-1278-3 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4700616/

PCPB shared its 2017 import data from KRA customs. The customs data revealed that Carbamate was also being imported into Kenya. This further makes the case of the urgent need to integrate KenTrade and KRA data bases. The use and resistance patterns of the four chemical groups imported into Kenya is hardly known. This represents an opportunity for public –private research partnerships involving research institutions, veterinary pharmaceutical companies and VMD. Research should focus on running efficacy trails under different application rates and in different livestock productions systems (intensive verses extensive). Socio economic drivers of farmers use of acaricides /pesticides should also be assesses. The importance of acaricide use is critical as indicated by the mapping study findings that highlighted that East Coast Fever (ECF) and babesiosis were still considered as important diseases that resulted in high economic losses for farmers. The study also revealed that antibiotics especially tetracyclines were unnecessarily being used to treat these two important tick-borne infections.

Anthelmintics resistance

Research and data on anthelmintic resistance in livestock is scanty in Kenya with resistance patterns mainly recorded for *Haemonchus* and *Ostertagia* species in small ruminants and cattle[53].The lack of systematic data collections means that efficacy of the two main anthelmintics groups that is benzimidazoles (albendazole) and Imidazothiazoles (levamisole) imported in 2017 in Kenya are still not known. The 2017 import data also revealed increased importation of salicylanilide (closantel, oxyclonazide and nitroxynil and injectable Ivermectin. There is need for research on efficacy of the current anthelmintic products in the market so as to provide evidence if the anecdotal reports of resistance are due to actual helminth resistance or un informed anthelmintic use.

Antibiotic resistance

Published and anecdotal reports indicate that antibiotic use in Kenyan livestock production systems is mainly (90%) for therapeutic purposes[54,55]. However, more investigation is warranted especially for poultry production systems since several

53 E O Mungube, L W Wamae, G A Omondi and G Mwangi (2015). Prevalence of multiple resistant Haemonchus and Ostertagia species in goats and cattle in Machakos, Eastern Kenya. Livestock Research for Rural Development 27 (12). http://www.lrrd.org/lrrd27/12/mung27237.htm

54 Global Antibiotic Resistance Partnership—Kenya Working Group. 2011. Situation Analysis and Recommendations: Antibiotic Use and Resistance in Kenya. Washington, DC and New Delhi: Center for Disease Dynamics, Economics & Policy.

55 Mitema,E.S.,G.M.Kikuvi,etal.2001.Anassessment of antimicrobial consumption in food producing animals in Kenya. Journal of Veterinary Pharmacology and Therapeutics 24:385---390.

surveys in Kenya and Tanzania also indicate that farmers rearing broilers and layers often use antibiotics to prevent diseases such as coccidiosis or Chronic respiratory disease (CRD) instead of effecting proper biosecurity and preventive vaccination practices[56, 57]. This observation was confirmed by the current survey that found that at retailer and private practitioners' levels monthly sales and use of oral antibiotic powders targeted for poultry species mainly tetracycline and sulfonamides surpassed any other antibiotics preparation form. It was also noted that at retailer level there was significant sale to poultry farmers of oral antibiotics with colistin and recent antibiotics molecules fosfomycin and radamycin. The mapping study found that the trend of importing specific antibiotic classes was somehow similar to the one reported in 2001, with imports of tetracyclines, aminoglycosides and penicillins being the top 4 highest antibiotic imports.

However, when you compare the 2001 and 2017 finding, Salinomycin is a new entrant that was not in the 2001 record. The product in 2017 recorded the second highest antibiotic import after tetracycline with aminoglycoside taking the third and penicillins the fourth position. The main differences however were in the quantities imported. In the 2001 study, the annual average tetracyclines import was 7,975 kilograms. In the current survey the 2017 tetracycline import request represented 64% of all antibiotic imports with quantities of 199,568 kilograms (Kgs). This represented a 2404% increase of imported tetracyclines intended for food animal use. A similar pattern was observed for Macrolides mainly Tylosin that moved from annual imports of 35 kgs in 2001 to 4,748 kgs in 2017. Aminoglycosides specifically streptomycin also had a similar increase that moved from an annual average of 958 kgs to 24,701 kgs. On the other hand, penicillins imports doubled from 904 kgs to 18,333 kgs while Sulfonamides remained relatively the same from 3,103 to 2,162 kgs. There was also no change in the fluoroquinolones class of antibiotics that remained under 95 kgs[58]. Interestingly, the 2017 KenTrade data had no records for Nitrofurans while the 2001 study found that this class of oral antibiotic was the second largest consumed at 1,499.96 kgs. The current survey findings indicate that tetracycline use in livestock production systems in Kenya is still very dominant, VMD will have to conduct more pharmacovigilance studies to understand if the reported diseases especially tick-borne disease in cattle, mycoplasma infections in cattle, goats and poultry are still sensitive to tetracycline-based products. Similar findings of tetracycline use have

56 Ezekiel P. Mubito, Francis Shahada, Martin E. Kimanya and Joram J. Buza. Antimicrobial use in the poultry industry in Dar-es-Salaam, Tanzania and public health implications. American Journal of Research Communication, 2014, 2(4): 51-63}

57 Benedict Omija (1991). Determination of oxytetracycline residue levels in eggs and meat of chicken using microbiological assay. University of Nairobi MSc.thesis in the department of Pharmacology and Toxicology.

58 Mitema,E.S.,G.M.Kikuvi,etal.2001.Anassessment of antimicrobial consumption in food producing animals in Kenya. Journal of Veterinary Pharmacology and Therapeutics 24:385---390.

been reported globally. In 2015, OIE using a digital questionnaire template launched the first annual data collection on the use of antimicrobial agents in animals in OIE Member Countries. A total of 130-member countries (72% of the 180 OIE Member Countries) submitted data for the years ranging from 2010 to 2015. The first phase results revealed that the main route of administration in animals was the oral route and tetracyclines and macrolides were the most commonly reported antimicrobial agents used globally in the 130 OIE member countries. However, the phase one data could not be compared in detail because the animal biomass data had not been collected[59]. To address this challenge OIE in 2016 during the second data collection phase, calculated for animal biomass for food-producing species, quantitative data was sourced for the year 2014 from the OIE World Animal Health Information System (WAHIS) and the Food and Agriculture Organization Statistics (FAOSTAT). The year 2014 was the target year as it had the highest number of submissions by OIE member countries of quantitative slaughter and live weight livestock data. This allowed OIE to conduct a global and regional analysis from 2013 to 2016. OIE estimates that the global antimicrobial agents used in animals in 2014 adjusted for animal biomass was 98.97 mg/kg, this figure was later adjusted for an upper level estimate of 134.31 mg/kg. Penicillin's were the most commonly reported antimicrobial class used. However, when data was differentiated by group of animals' species it was found that tetracyclines were the most commonly reported antimicrobial class used in terrestrial food-producing animals[60]. The OIE global findings and the current VMD survey results indicate that use of third generation cephalosporins was not common and where used it was either as injectable preparations targeted to manage respiratory or acute mastitis conditions in dairy animals or as Intramammary preparations. This is an important finding as this class of antibiotic is among the last line of defence when faced with antibiotic resistant infections in animals[61]. However, it confirms recent studies of mastitis

59 OIE annual report on the use of antimicrobial agents in animals better understanding of the global situation (2016) First report. Accessed from http://www.oie.int/scientific-expertise/veterinary-products/antimicrobials/

60 OIE annual report on the use of antimicrobial agents in animals better understanding of the global situation (2017) Second report. Accessed from http://www.oie.int/scientific-expertise/veterinary-products/antimicrobials/

61 European Medicines Agency, European Surveillance of Veterinary Antimicrobial Consumption, 2017.'Sales of veterinary antimicrobial agents in 30 European countries in 2015'. (EMA/184855/2017)

in Kenya that indicate that mastitis causing organisms are becoming more resistant to most of antibiotic classes[62,63].

Antimicrobial resistance situation analysis

Multidrug resistant bacteria have been detected in Kenya in both meat and fresh vegetable produce as well as in humans in contact with livestock. The causes of antimicrobial resistance (AMR) in developing countries are complex and may be rooted in practices of all actors in the human and animal health supply chain. However, the biggest driver is the lack of appropriate regulations in the sales of antibiotics that results in over the counter access thus increasing misuse. It has also been shown that many human and veterinary antimicrobials dispensed in Africa are of questionable pharmacological quality. The adverse climatic conditions such as high ambient temperatures and humidity affects the overall quality of the antimicrobials during storage, thus increasing the risk of drug degradation and reduced efficacy. The problem of counterfeit products in which the drug may contain little or no active substance of the antimicrobial ingredient, or the wrong substance is also another key AMR driver[64]. The antibiotic resistance drivers mentioned in literature are similar to those mentioned by the current survey respondents with more than 80% of respondents at all levels in the supply chain indicating they were aware of AMR and considered it a serious problem. Strategies proposed in literature to contain or minimize the development of antibiotic resistance in livestock production systems include;

- Promotion of good hygiene and sanitation practices,
- Increase vaccination coverage of herds,
- Research on alternative therapies,
- Education and awareness creation on AMR across the livestock value chain
- Promotion of judicious use and antimicrobial stewardship amongst animal health professionals[65].

62 Gitau, G.K., Bundi, R.M., Vanleeuwen, J. & Mulei,C.M., 2014, 'Mastitogenic bacteria isolated from dairy cows in Kenya and their antimicrobial sensitivity. Journal of the South African Veterinary Association 85(1). Art. #950, 8 pages. http://dx.doi.org/10.4102/jsava.v85i1.950

63 P N Ndirangu, D Siamba, H O Wesonga, E O Mungube, M W Maichomo, J M Mugambi (2017). Prevalence of bovine mastitis and multi-antibiotic resistant Staphylococcus and Streptococcus species in a research centre farm at Naivasha, Kenya. Bulletin of Animal Health and Production in Africa 65:2.

64 James A. Ayukekbong, Michel Ntemgwa and Andrew N. Atabe (2017). The threat of antimicrobial resistance in developing countries: causes and control strategies. Antimicrobial Resistance and Infection Control 6:47. https://doi.org/10.1186/s13756-017-0208-x

65 The OIE Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials (November 2016. http://www.oie.int/amrstrategy

The above strategies have been proven to work, for example, the European Medicines Agency (EMA) in 2017 published a report on the sales of veterinary antibiotics between 2010 and 2015 in Europe. The report showed a 30% decrease in sales of veterinary antibiotics. The reduced antibiotic use trend demonstrates that EU national campaigns promoting prudent use of antibiotics in animals is starting to pay off [66].

Establishing AMR surveillance and monitoring systems

The global push for judicious use of veterinary antimicrobials cannot be effected without data on antimicrobial use and resistance[67]. The main challenge faced when quantifying antimicrobial use is that there is no scientifically reached consensus regarding which data should be collected and how it should be recorded. However, the lack of harmonisation and standards is currently being addressed with Europe taking the lead. Some of the technical units used to measure AMU at European level include Animal Daily Dose (ADD), the Defined Daily Dose (DDD), Population Correction Unit (PCU) or mg/kg, "Treatment frequency," or "Therapy index". The progress and milestones achieved by the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project should therefore be a starting point for countries as they set up AMU surveillance and monitoring systems[68]. The current survey conducted by VMD in 2017 section laid bare the challenges faced in trying to conduct a country wide baseline survey. This is because the public sector has limited staff and resources to conduct such an exercise. In addition, best practices learned from similar efforts conducted by the European Medicines Agency (EMA) demonstrate that it is important to include a wide range of different professionals from the planning stage the team should include Information Technology (IT) experts such as computer programmers well versed with modelling to social scientists as well as human and veterinary professionals. The data collection tool should also be in digital form to

66 European Medicines Agency, European Surveillance of Veterinary Antimicrobial Consumption, 2017.'Sales of veterinary antimicrobial agents in 30 European countries in 2015'. (EMA/184855/2017)

67 Carmo LP, Schüpbach-Regula G, Müntener C, Chevance A, Moulin G, Magouras I. Approaches for quantifying antimicrobial consumption per animal species based on national sales data: a Swiss example, 2006 to 2013. Euro Surveill. 2017;22(6):pii=30458. DOI: http://dx.doi.org/10.2807/1560-7917.ES.2017.22.6.30458

68 Pinto Ferreira J (2017) Why Antibiotic Use Data in Animals Needs to Be Collected and How This Can Be Facilitated. Frontier Veterinary Science 4:213. https://www.frontiersin.org/articles/10.3389/fvets.2017.00213

allow a standardized framework that will be able to capture antimicrobial consumption use across the veterinary antimicrobial supply chain with minimal entry errors[69,70].

Barriers to compliance to set VMD regulation

The important role played by government and regulatory agencies to mitigate AMR development is crucial and cannot be understated. Kenya is one of the few LMIC countries that are at the forefront in developing legal frameworks to mitigate AMR development. The country has a national policy on prevention and containment of antimicrobial resistance as well as an action plan and regulatory agencies in both the human (PPB) and animal health sector (VMD)[71]. The current survey respondents noted that the main hindrance to compliance was the cost required to acquire legal licenses to import, retail or set up veterinary practices. In addition, the lack of prosecution of defaulters discouraged most actors and hence increased incidences of non-compliance for new entry actors in the supply chain. This means that in Kenya, as in most LMICs, the main barrier to compliance is not lack of a legal or regulatory framework but the lack of human and financial resources to enforce policies and to impose penalties on defaulters. The government agencies also lack resources to identify counterfeit drugs or verify the quality of locally manufactured or imported drugs.

Conclusion and way forward

The current efforts made by VMD to set up a surveillance system on antibiotic use in food producing animals is a step in the right direction and should be supported. However, in order for the surveillance data to be effective VMD needs to take into consideration the following recommendations:

69 Pinto Ferreira J (2017) Why Antibiotic Use Data in Animals Needs to Be Collected and How This Can Be Facilitated. Frontier Veterinary Science 4:213. https://www.frontiersin.org/articles/10.3389/fvets.2017.00213

70 Schar D, Sommanustweechai A,Laxminarayan R, Tangcharoensathien V (2018). Surveillance of antimicrobial consumption in animal production sectors of low- and middle-income countries: optimizing use and addressing antimicrobial resistance. PLoS Med 15(3): e1002521. https://doi.org/10.1371/journal.pmed.1002521

71 National Policy for the Prevention and Containment of Antimicrobial Resistance, Nairobi, Kenya: Government of Kenya, May 2017.

In the short term,

1. There is an urgent need to streamline the bureaucratic process of acquiring multiple licences and certification at national and county level. VMD should spearhead discussions on this at national and county level.
2. Future AMU surveys should engage a multi-disciplinary team from the start composed of IT experts, social scientist, statisticians and animal health professionals. This will ensure a more robust and inclusive sampling procedure, standardised and digitalised data collection tool.
3. The veterinary medicine directorate will need to spearhead harmonisation of VMP import data at KenTrade as well as lobby for linking of KRA customs data with KenTrade and VMD data bases. This will allow VMD to accurately capture and track VMP imports.
4. Future AMU surveys should be done in pilot or sentinel sites. The criteria of site selection should be clearly defined and based on evidence gathered. In addition, each sentinel county site should include all actors in the veterinary medicine product supply chain.
5. There is need for a common communication strategy on AMU and AMR targeted for the animal and human sectors. Awareness creation on AMR should be a joint effort with animal health professional associations, veterinary pharmaceutical companies and county governments.
6. The Kenya Veterinary Board in partnership with VMD should give guidelines on how to train animal health professionals on prudent and judicious use of antimicrobials. The trainings should also be geared towards advocating for laboratory diagnosis before treatment and instituting preventive measures such as vaccination and increased biosecurity in livestock production systems.
7. In the spirit of transparency advocated for by OIE. VMD should ensure that the findings of the baseline mapping study and the OIE AMU self-reporting findings are published and made open access.
8. The human and veterinary medicine regulatory agencies need to lobby for enforcement of existing laws that advocate for prescription dispensing of human and veterinary antibiotics.

In the long term

1. The veterinary medicine directorate should hire more staff, train them on inspections and devolve them to counties to ensure prosecution of unqualified persons running unlicensed VMP retail outlets.

2. The VMD should foster partnership with research institutions and animal health professional associations to develop treatment protocols for notifiable livestock disease. The protocols should clearly outline first, second and last resort line treatments for each disease. VMD should also spearhead the development of a Kenya Veterinary Medicinal Products handbook or Kenya Veterinary Medicines Formulary.
3. VMD should continue to participate in discussions and activities spearheading the setting up of laboratory infrastructure for AMR and drug residue surveillance.
4. Promote public-private partnerships to conduct continuous surveillance and efficacy trials on acaricides and anthelmintic.

Annex section

Annex 1: Consent Form

Telephone: 020 – 8043441
E-mail: infodvs@kilimo.go.ke

Veterinary Research
Laboratories
Private Bag, Kangemi 00625
Nairobi

REPUBLIC OF KENYA
MINISTRY OF AGRICULTURE, LIVESTOCK & FISHERIES
STATE DEPARTMENT OF LIVESTOCK
Office of the Director of Veterinary Services

Consent to participate in the survey of Veterinary Medicines Use and Practices in Kenya.

As part of our efforts to improve veterinary services in the country, the DVS, with support from the Food and Agriculture Organization of the United Nations, (FAO) is conducting a survey to understand the veterinary medicines supply chain. The survey seeks to establish the patterns and trends in veterinary pharmaceutical acquisition, prescription and administration to livestock and eventual disposal. To achieve this, we are gathering information from importers, manufacturers, distributors and retailers of veterinary medicines as well as animal feed manufacturers and consumers of these pharmaceuticals. The aim of this survey is to enable evidence-based policy decisions and actions in the regulation of veterinary medicines. This will enhance animal health and welfare, which directly impacts public health.

Your participation in this survey is voluntary and you are free to stop the survey at any time, should you wish.

All responses will remain anonymous and are completely confidential.

The information that you provide will be maintained and analyzed by the office of the DVS together with FAO. Data will not be made available to other parties.

If you are willing to participate in this survey, kindly affix your signature below,

Name ……..

Sign ……..

Date ……..

Annex 2: Questionnaire: Importer /Manufacturer/Distributor

About You and Your Company

1. County.....
2. City/Town.....
3. Name of Respondent.
   (Optional).....
4. Name of Company
   (Optional).....
5. Address (Optional).....Tel.....Email.....
6. GIS Coordinates (optional) Long .....Lat.....
7. Position in the Company.....
8. Nature of Business
   a. Importer of API
   b. Importer of finished products
   c. Importer of both API and finished products
   d. Manufacturer / repackaging
   e. Distributor
9. What licenses or certificate do you require to carry out this business?
   a. GMP
   b. WDL
   c. NEMA
   d. Manufacturing license
   e. Single business permit
10. Others (fire, premise,
    health,).....
11. Of these, which ones do you currently
    possess?.....
12. How easy is it to acquire the licenses mentioned in question nine above...?
13. If not easy, Why?.....
14. What range of Veterinary medicinal Products do you deal with?

Item	Quantity (kgs per year)	Remarks
a. Antibiotics		
b. Acaricides		
c. Anthelmintics		
d. Others (specify)		

15. If antibiotics, what molecules do you deal with?

Molecule	**Quantity (kgs) per year**	**Exporting country**	**manufacturing country**	**Remarks**

16. Mode of importation (transport)
    a. Air
    b. Sea
    c. Land
17. What is the port of entry?.....

18. Describe your stock control and management system.....
19. Do you store all your products in one place? If not, where else?.....
20. How do you manage access to the warehouse and on the premise? .....
21. Is temperature monitored and controlled in your store?.....
22. Do you have a pest management plan? .....
23. How do you deal with expired products? .....
24. Do you have a quarantine plan? .....
25. If yes, it is for which kind of products?.....
26. In your opinion, what is the main barrier to compliance with existing laws and regulations in this sector?.....
27. What, in your opinion needs urgent intervention to make the situation better? .....

Thank you for your time

Annex 3: Feed Millers questionnaire

About You and Your Company

1. County.....
2. City/Town.....
3. Name of Respondent. (Optional).....
4. Name of Company (Optional).....
5. Address (Optional) Box .....Tel..... Email.....
6. GIS Coordinates Long (Optional).....Lat.....
7. Position /Title in the Company.....
8. What kind of products do you produce? (tick all that apply)
    - ☐ Complete feed
    - ☐ Mineral licks
    - ☐ Feed supplements
    - ☐ Premixes
    - ☐ Feed ingredients
9. What is your monthly production capacity? ……Tons
10. Do you produce medicated feeds or feed supplements? ☐ Yes ☐ No

11. If yes, do you produce your medicated premix? ☐ Yes ☐ No
12. What veterinary medicinal product (VMP) do you commonly use? …….
13. In which products do you use the VMP? (tick all that apply)

☐ Dairy feed ☐ poultry feed ☐ pig feeds ☐ fish feeds

Molecule	In which Products	Quantity used per year	Remark

14. where do you source the medicated premixes
    - ☐ Own production,
    - ☐ Local pharmaceutical companies
    - ☐ Imports
    - ☐ Other (specify)……
15. To Whom do you sell the medicated feeds

Buyer	**% of total sales**	**Remark**
Agrovets		
Other feed retailers		
Vets and paravets		
Directly to farmers		
Dairy cattle farmers		
Poultry farmers		
Pig famers		
Others (specify)		

16. If your company produces medicated premixes , to whom do you sell

☐ Individual farmers ☐ agro-ve ☐ feed millers ☐ others (specify)

17. Have your medicated feeds / supplements sales during the last one year increased, decreased or stayed the same compared to the previous year? (choose only one)
    - ☐ Increased
    - ☐ Decreased
    - ☐ No change
18. If the sales volume is higher or lower what do you think is the most important reason for this change? (choose only one)
    - ☐ More demand from customers
    - ☐ Less institutional procurement procedures
    - ☐ More supply coming from suppliers
    - ☐ Less demand from customers
    - ☐ More institutional procurement procedures
    - ☐ Less supply coming from suppliers
    - ☐ Other (Specify)
19. What/which are the two most common conditions that the medicated feed or feed supplement is sold to treat? (List them?)
20. In your opinion, what is the main reason most people do not obey existing laws and regulations in this sector?

Thank you for your time

Annex 4: Retailer questionnaire

About You and Your Company

1. County.....
2. City/Town.....
3. Name of Respondent. (Optional).....
4. What is your highest academic qualification?
   - ☐ Bachelor of Veterinary Medicine
   - ☐ Other animal health related degree (animal production, animal health etc.)
   - ☐ Diploma in Animal Health
   - ☐ Certificate in Animal Health
   - ☐ Other animal health unrelated qualification
   - ☐ Secondary education
   - ☐ Primary education
   - ☐ No formal education
5. Name of Company (Optional).....
6. Address (Optional) Box.....Tel.....
   Email.....
7. GIS Coordinates: Long .....Lat.....
8. Position (title) in the Company.....
9. Nature of Business
   a. Agrovet
   b. Animal feed retailers
   c. Franchise (e.g. Sidai)
   d. Dairy cooperatives
   e. Pharmacies/ chemists
   f. Mobile retailers (briefcase retailers)
   g. Vets and Para-veterinarians
   h. Sales reps in vans (from licensed pharmaceuticals)
   i. CBOs
   j. FBOs
   k. NGOs
   l. Farmers
   m. Livestock traders
   n. County Government
   o. Community Disease Reporters
   p. Community leaders

10. What antibiotics do you sell?
    (list all)

11. Questions about **Tetracycline** injectable

Concentration of active ingredient (s)	**Volume**	**Vials per month**	**Supplier** - 1. Pharmaceutical companies - 2. Other agrovets - 3. Franchise - 4. Other (specify)	**Whom do you sell to?** - 1. Vets & paravets - 2. Feed manufacturers - 3. Farmers – intensive - 4. Farmers - Extensive - 5. Vet clinics - 6. Others (specify)	**Remarks**
5%	50ml				
5%	100ml				
5%	250ml				
5%	500ml				
10%	50ml				
10%	100ml				
10%	250ml				
10%	500ml				
20%	50ml				
20%	100ml				
30%	50ml				
30%	100ml				

11. Questions about **other injectables**

Antibiotic (trade name)	**Concentration of active ingredient (s)**	**Volume**	**Vials per month**	**Supplier** - 1. Pharmaceutical companies - 2. Other agrovets - 3. Franchise - 4. Other (specify)	**Remarks**

12. Questions about **antibiotic sprays**

Spray (trade name)	**Concentration of active ingredient (s) (mg/gm)**	**Volume per can (mls)**	**Cans per month**	**Supplier** - 1. Pharmaceutical companies - 2. Other agrovets - 3. Franchise - 4. Other (specify)	**Remarks**

13. Questions about **intra-mammary tubes**

Trade name	**Concentration of active ingredient (s) (mg/gm)**	**Volume per tube (mls)**	**Tubes per month**	**Supplier** - 1. Pharmaceutical companies - 2. Other agrovets - 3. Franchise - 4. Other (specify)	**Remarks**

14. Questions about other **antibiotics (tablets, capsules, pessaries, boluses, topicals)**

Trade name	**Concentration of active ingredient (s) (mg/gm)**	**Quantity per each**	**Quantity per month**	**Supplier** - 1. Pharmaceutical companies - 2. Other agrovets - 3. Franchise - 4. Other (specify)	**Remarks**

15. Do you sell medicated animal feeds and medicated supplements? ☐ Yes ☐ No

16. If yes, tick all that apply:

q. Medicated complete feed
r. Medicated mineral licks
s. Medicated feed supplements
t. Medicated premixes

17. If yes, who do you buy from and sell to (fill in the table)?

Product	**Supplier** - 1. Feed manufacturers - Stockists - 2. Other agrovets - 3. Franchise - 4. Other (specify)	% of total sales	**Buyer** 1. Agrovets 2. Other feed retailers 3. Vets and paraprofessional 4. Directly to dairy farmers 5. Directly to Poultry farmers 6. Directly to pig farmers 7. Others (specify)	Remarks
Medicated chick mash				
Medicated Growers mash				
Medicated mash				
Medicated starter mash				

Medicated broilers Mash				
Medicated dairy meal				
Medicated pig meal				
Medicated mineral licks				
Medicated feed supplements				

18. When selling antibiotics to customers, which information do you give them?
19. What/which are the five most common conditions antibiotics are sold to treat? (List them?)
20. Do you keep records of those you sell antibiotics to? (choose one)
    - ☐ Always
    - ☐ Sometimes
    - ☐ Never
21. What factors do you take into account when recommending a certain antibiotic to a customer? (tick all that apply) (Rank)
    - ☐ Price
    - ☐ Availability
    - ☐ Efficacy
    - ☐ Recommended antibiotic choice
    - ☐ Customer preference
22. How do you store your antibiotics? (tick all that apply)
    - ☐ Fridge
    - ☐ Cupboard
    - ☐ Open shelves
    - ☐ Cool box
    - ☐ Other
23. What do you understand about AMR?
24. In your opinion, what is the main barrier to statutory compliance?
25. What, in your opinion needs urgent intervention

Thank you for your time

Annex 5: Veterinary Clinics and Practitioners questionnaire

About Yourself

1. County.....
2. Sub County.....
3. Nearest town …….
4. Sub location……..
5. Name of Respondent. (Optional).....
6. Age ……..
7. Sex……
8. What is your highest academic qualification?
    a. Bachelor of Veterinary Medicine
    b. Other animal health related degree (animal production, animal health etc.)
    c. Diploma in Animal Health

d. Certificate in Animal Health
e. Other animal health unrelated qualification (specify)

9. Business type ……..
   a. Agrovet
   b. Clinic
   c. Freelance (private)
   d. Government vet
   e. Other (specify) …….
10. What type of management system do majority of your clients practice?
   a. Intensive
   b. Semi intensive
   c. Extensive (free range pigs and Poultry, pastoralism)
11. What Type of enterprise

Livestock kept	Main health challenges (diseases)	Medicine (Trade name)	Active ingredient	Quantity (per Month)
Dairy	1.			
	2.			
	3.			
Layers	1.			
	2.			
	3.			
Broilers	1.			
	2.			
	3.			
Pigs	1.			
	2.			
	3.			
Kuku Kienyeji	1.			
	2.			
	3.			
Beef	1.			
	2.			
	3.			
Small ruminants	1.			
	2.			
	3.			
Camels	1.			
	2.			
	3.			
Others (specify	1.			
	2.			
	3.			

12. How do you arrive at the diagnosis and treatment of the health conditions stated above?
   a. Clinical diagnosis

b. Lab testing
c. Guess work

13. Where do you obtain medicines?
    a. Agrovet
    b. Franchise (e.g. Sidai)
    c. Dairy cooperatives
    d. Pharmacies/ chemists
    e. Mobile retailers (briefcase retailers)
    f. Vets and Para-veterinarians
    g. Sales reps in vans (from licensed pharmaceuticals)
    h. CBOs
    i. FBOs
    j. NGOs
    k. County Government
    l. Others (specify)…….
14. How do you dispose unused or expired medicines?
    a. Keep them
    b. In the toilet
    c. Bury them
    d. Rubbish pit
    e. Throw in open farms
    f. Others (Specify)
15. In your opinion, what are the main challenges in achieving treatment success?
16. What do you understand about AMR?
    -In your opinion, how serious is the AMR problem?
17. In your opinion, what is the main barrier to statutory compliance?
18. What, in your opinion needs urgent intervention.....

Thank you for your time

Annex 6: Livestock Keeper/ Farmers questionnaire

About Yourself

1. County.....
2. Sub County.....
3. Nearest town …….
4. Sub location……..
5. Name of Respondent. (Optional).....
6. Age ……..
7. Sex……
8. What is your highest academic qualification?
    f. University
    g. Tertiary college
    h. High School
    i. Primary Education
    j. Other qualification (specify)……
9. Type of farming……..
    a. Ranching
    b. Pastoralism
    c. Mixed farming

d. Poultry Farming
e. Pig Farming
f. Other (specify) …….

10. What type of management system do you practise?
    a. Intensive
    b. Semi intensive
    c. Extensive

11. Type of enterprise

Livestock kept	Main health challenges (diseases)	Medicines used (Trade name)	Quantity (per Month)
Dairy	1.		
	2.		
	3.		
Layers	1.		
	2.		
	3.		
Broilers	1.		
	2.		
	3.		
Pigs	1.		
	2.		
	3.		
Kuku Kienyeji	1.		
	2.		
	3.		
Beef	1.		
	2.		
	3.		
Small ruminants	1.		
	2.		
	3.		
Camels	1.		
	2.		
	3.		
Others (specify	1.		
	2.		
	3.		

12. How do you arrive at the diagnosis and treatment of the health conditions stated above?
    a. Clinical diagnosis
    b. Lab testing
    c. Peer advice
    d. Guess work

13. Do you obtain a prescription from a Veterinarian /AHA for you to purchase the medicines?
    Yes ☐ No ☐

14. Where do you obtain your medicines?

a. Agrovet
b. Franchise (e.g. Sidai)
c. Dairy cooperatives
d. Pharmacies/ chemists
e. Mobile retailers (briefcase retailers)
f. Vets and Para-veterinarians
g. Sales reps in vans (from licensed pharmaceuticals)
h. CBOs
i. FBOs
j. NGOs
k. County Government

15. Others (specify)How do you dispose of unused or expired medicines?
    a. Keep them
    b. In the toilet
    c. Bury them
    d. Rubbish pit
    e. Throw in open farms
    f. Others (Specify)
16. In your opinion, what are the main challenges in achieving treatment success?
17. In your opinion, what is the main reason for self-diagnosis and treatment?
18. What, in your opinion needs urgent intervention to rectify the situation above?

Thank you for your time

Annex 7: Consultative meeting participants

No	Name	Organization
1	Dr. Nathan Songok	Interim VMD Secretariat
2	Dr. Naphtal Mwanziki	Interim VMD Secretariat
3	Dr. Adelaide Ayoyi	Interim VMD Secretariat
4	Dr. Emily Muema	Interim VMD Secretariat
5	Dr. Jane Lwoyero	DVS, AMR Focal Point
6	Dr. Joyce Thaiyah	DVS-VPH- Animal Feeds
7	Dr. Hesbon Amenya	DVS-CVL-Chemistry Lab
8	Dr. Indraph Ragwa	KVB
9	Dr. Githaiga Wagate	PCPB
10	Dr Josphat Muturi	Coopers (K) Ltd
11	Ms Teresia Wangare	University of Nairobi
12	Mr. Felix Mungai	HighChem Essentials
13	Dr. Jafred Kitaa	University of Nairobi
14	Prof. James Mbaria	VMD Council
15	Dr. Ken Mbogori	VMD Council
16	Dr. Josiah Mandieka	VMD Council
17	Mr. Moses Kiogora	VMD Council
18	Dr. Joseph Odhiambo	Norbrook (K) Ltd

19	Dr. Maurice Msanya	Bimeda (K) Ltd
20	Dr. David Ngugi	Murphy Chemicals
21	Prof. Folorunso Fasina	FAO
22	Prof. Eric Fevre	ILRI
23	Stephen Gikonyo	FAO
24	Dr Tabitha Kimani	FAO
25	Dr. Rezin Odede	Sidai