REPUBLIC OF KENYA

NATIONAL POLICY ON PREVENTION AND CONTAINMENT OF ANTIMICROBIAL RESISTANCE

APRIL 2017

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FOREWORD

Antimicrobial resistance (AMR) is a global threat that requires urgent collaborative action within and among countries. AMR makes standard treatments ineffective and facilitates the spread of antimicrobial resistant infections rendering communities vulnerable.

The Ministry of Health (MOH) and Ministry of Agriculture, Livestock, Fisheries & Blue Economy (MALF) recognized antimicrobial resistance as a priority following findings from status reports and studies from Ministries, Departments, Agencies and Stakeholders.

Following reports of alarming rates of antimicrobial resistance to hospital and community-acquired infections and in the Agricultural Sector, the Global Action Plan (GAP) on AMR was adopted in 2015. This followed decisions made by the World Health Assembly, the FAO Governing Conference and the World Assembly of OIE Delegates to jointly combat AMR. Member states committed to develop national action plans on AMR that are consistent with the Global Action Plan, and to implement relevant policies and plans to prevent, control and monitor AMR.

The Ministries responsible for Health and Agriculture appointed a multi sectoral Technical Working Group, following the advice of the National Antimicrobial Stewardship Advisory Committee in 2016 to develop the AMR Policy and National Action Plan.

Through a 'One Health' platform that embraces interdisciplinary collaboration and communication, the government undertakes to implement this policy in all aspects of health care for humans, animals and the environment.

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Finally, we appreciate the tireless efforts of the Technical Working Group comprising of Dr. Rachel Kamau, Dr. Eveline Wesangula, Mr. Stephen Cheruiyot, Dr. Jared Nyakiba, Ms. Susan Githii, Dr. Allan Azegele, Dr. Jane Lwoyero and Dr. Christopher Wanga, Dr. Nathan Songok, Dr. Naphtali Mwanziki, Ms. Daisy Muriuki Ms. Teresia Karanja and Prof. Samuel Kariuki.

EXECUTIVE SUMMARY

Antimicrobial resistance is a global public health concern that has threatened the very core of modern medicine and effective response to infectious diseases. Effective antimicrobial drugs are vital for both preventive and curative measures, protecting patients from potentially fatal diseases and ensuring that treatment, complex procedures, such as surgery and chemotherapy, can be provided at low risk. The misuse and overuse of these antimicrobials in human medicine and food production have put every nation at risk considering that very few antimicrobial agents are in development. Without concerted and immediate action on a national scale, Kenya stands to diminish the tremendous gains made in the fight against infectious diseases.

Data from sentinel sites indicate high rates of resistance for respiratory, enteric and hospital acquired infections indicating that many available antimicrobial regimens such as penicillins and cotrimoxazole are unlikely to be effective against common infections. In livestock, antimicrobial resistance has been reported in *E. coli* isolates from beef and poultry showing resistance to common antimicrobial agents such as tetracycline, co-trimoxazole, streptomycin, ampicillin, quinolones and third generation cephalosporins at varying frequencies.

In response to this, the Ministries responsible for Health and Agriculture, appointed a Technical Working Group to lead the development of this policy. National Consultative stakeholder engagement was done culminating in a national validation workshop.

The policy adopted by the government comprises the following: the introduction, rationale, policy goals and objective, challenges, policy interventions and the implementation framework. The proposed policy interventions address the following objectives: Improving awareness and understanding of antimicrobial resistance;

Strengthening the knowledge and evidence base on AMR; reducing the incidence of infection; Optimizing the use of antimicrobials in human, animal and plant health; and supporting sustainable investment in new medicines, diagnostic tools, vaccines and other interventions.

The policy recognizes the diversity in the different sectors and emphasizes that an all out effort is needed to effectively combat AMR.

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ACRONYMS AND ABBREVIATIONS

AMR	Antimicrobial Resistance
AMU	Antimicrobial Use
APH	Agriculture and Public Health
ASTs	Antimicrobial Susceptibility Testing
AU-IBAR	African Union Inter-Africa Bureau of Animal resources
CAC	Codex Alimentarius Commission
CDC	Centre for Disease Control and Prevention
COMESA	Common Market for Eastern and Southern Africa
EAC	East African Community
ESBL	Extended Spectrum B-Lactamase
FAO	Food and Agriculture Organization
GAP	Global Action Plan
GARP-K	Global Antimicrobial Resistance Partnership-Kenya
GDP	Gross Domestic Product
GFN	Global Foodborne Infection Network
HCW	Health Care Worker
ILRI	International Livestock Research Institute
IPC	Infection Prevention and Control
KAP	Knowledge Attitude and Practices
KEML	Kenya Essential Medicines List
KEMRI	Kenya Medical Research Institute
KEPHIS	Kenya Plant Health Inspectorate Services
MALF	Ministry of Agriculture Livestock and Fisheries
MoH	Ministry of Health
MRSA	Methicillin Resistant *Staphylococcus aureus*

NAP	National Action Plan
NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NEMA	National Environmental Management Authority
NGO	Non- Governmental Organization
NMRL	National Microbiology Reference Laboratory
NPHL	National Public Health Laboratories
NQCL	National Quality Control Laboratories
NTS	Non- typhoidal Salmonella
OIE	World Organization for Animal Health
PPB	Pharmacy and Poisons Board
QA	Quality Assurance
QC	Quality Control
SOPs	Standard Operating Procedures
STGs	Standard Treatment Guidelines
TWG	Technical Working Group
UoN	University of Nairobi
WHO	World Health Organization
WTO	World Trade Organization

CHAPTER ONE – INTRODUCTION

1.1 Background

Antimicrobial agents are medicines used in humans, animals and plants for both prevention and treatment of infectious diseases. Antimicrobial resistance occurs when disease causing microorganisms such as bacteria, viruses, fungi and parasites are no longer responsive to previously effective antimicrobial agents.

Antimicrobial agents used to treat various infectious diseases in animals and plants are the same or similar to those used in humans. Their availability and use in both sectors has been and is essential for public health, national wealth creation, food security, food safety, human and animal welfare, protection of livelihoods, and sustainability of animal and plant production. Antimicrobial agents therefore play a critical role in safeguarding human health, animal health, food security and global trade.

In the 1940s, the introduction of antimicrobial agents into medical practice revolutionized the ability to treat infectious diseases. However, when micro-organisms become resistant to medicines, the options for treating the diseases they cause are reduced. Overuse, misuse, improper disposal and counterfeiting of antimicrobials have contributed to accelerated development of AMR in microorganisms that cause diseases.

AMR is a global concern for both the Public Health and Agriculture Sectors. Globally it is projected that by 2050, the health consequences and economic costs of AMR are estimated at 10 million annual human fatalities and a 2 to

3.5 percent decrease (equivalent to USD 100 trillion) in global Gross Domestic Product (GDP).

AMR requires immediate and urgent attention and action as the direct consequences of infection with resistant microorganisms can be severe including longer illnesses, increased mortality, prolonged hospital stays and increased costs. The indirect impact of AMR spans beyond health risks and has wide implications on the development agenda. AMR will drain global and national economies with increased economic losses due to reduced productivity caused by sickness of both humans and animals. Therefore, AMR increases morbidity, mortality, and health care costs, threatens health security, food security and negatively impacts on trade and economies.

To counter the effects of AMR, long term investment in financial and technical support is required to strengthen public health systems to ensure appropriate use and access to antimicrobial agents. This calls for concerted action on a global and national scale to prevent the world from returning to a pre-antibiotic era in which common infections will once again kill with abandon.

This Policy aims at prevention and containment of antimicrobial resistance in Kenya, through implementation of the AMR National Action Plan.

1.2 Situational Analysis

1.2.1 The Extent of the Antimicrobial Resistance

AMR has become a global health priority due to its high impacts on human and animal health, food safety and sustainable development of the agricultural sector. Resistance arising in one geographical location or species can spread with ease to other geographical locations or spillover in other species.

Worldwide, statistics from the industrialized economies show that antimicrobials are extensively used in agriculture and in public health. This trend is likely to be recorded in low and middle income countries where rapid growth in populations with incidence of infectious diseases coupled with high demand for animal proteins sourced from intensive farming systems leads to increased antimicrobial use.

It is now widely acknowledged that the rate at which AMR is developing and spreading far outstrips the rate at which new antimicrobial drugs are being developed.

Several studies and reports have been undertaken in Kenya, which have documented trends in Antimicrobial Use (AMU) and AMR in humans and animals. From the findings, Kenya is already experiencing increasing levels of antimicrobial resistance. Due to a lack of systematic surveillance, the exact burden of AMR in Kenya is unknown.[1]

Resistance has been reported in key bacterial pathogens including methicillin resistant *Staphylococcus aureus (MRSA)* from hospitalized patients, reduced susceptibility of community acquired pneumococci; multi-drug resistant extended spectrum beta lactamase producing *Salmonella typhimurium* and *Vibrio cholerae* from outbreaks in Kenya. With increasing resistance to

[1] Situational Analysis; Antibiotic Use and Resistance in Kenya 2011.

fluoroquinolones also reported in typhoid outbreaks limiting treatment options for these infections[2].

Studies in the livestock sector, indicate that *E. coli* isolates from beef and poultry have been shown to be resistant to tetracycline, co-trimoxazole ,streptomycin, ampicillin, quinolones and third generation cephalosporins at varying frequencies. Some of the isolates were found to be resistant two or three antimicrobials[3].

Surveillance systems to monitor efficacy of antimicrobial agents used in TB, HIV and Malaria exist and these systems need to be interlinked with the National AMR surveillance system.

It is notable that key antimicrobial-resistant food borne pathogens (*E. coli*, *Salmonella enterica* and *Campylobacter* spp) have occurred with increasing frequency as causes of food-borne diseases ranging from mild gastroenteritis to life threatening systemic infections, such as those caused by non-typhoidal salmonella (NTS). These infections are considered as public health problems of global significance[4].

1.2.2 Drivers of Antimicrobial Resistance

The underlying causes of AMR and current barriers to addressing it include: limited awareness of its implications in human and animal health among the general public, policy makers and animal and public health practitioners; high burden of infectious diseases due to impoverished living conditions of many people; high HIV/AIDS burden and poor infection control practices in hospitals; high burden of diseases in animals associated with poor husbandry practices and low vaccination coverage levels; medicated animal feeds; weak healthcare systems in which many people lack access to

[2] Situation Analysis; Antimicrobial Use and Resistance in Kenya 2016.
[3] Kariuki S, et al. FAO/WHO Project Report: Improving Food Safety in Meat Value Chains in Kenya. Food Protection Trends 2013; 33:172-175
[4] Kariuki S, Onsare RS. Epidemiology and Genomics of Invasive Nontyphoidal Salmonella Infections in Kenya. Clin Infect Dis. 2015;61 Suppl 4:S317-24.

services; antimicrobial misuse and overuse as a result of easy over the counter(OTC) access and high levels of self-medication; unreliable access to medicines and diagnostics ; weak surveillance systems; poor enforcement of regulation; inadequate investment in laboratory infrastructure, diagnostic tools and human resources; and inadequate research and development of new antimicrobials, diagnostics and vaccines . AM Research is seen as a less attractive business investment than that of medicines for chronic diseases.

The Knowledge, Attitude and Practice analysis among healthcare workers at different levels of healthcare revealed a general awareness of AMR and its effects on society, but the utilization of this knowledge to prevent AMR in clinical practice was lacking. Poor access to microbiology laboratory services, scarcity of resources and lack of quality assurance for antimicrobial susceptibility data were cited as important factors leading to lack of AMR data and therefore poor implementation of prudent AMU in public health.

In livestock production little or no access to affordable veterinary services including consultancies and laboratory testing has often been cited as an important factor leading to over the counter purchase of antimicrobials and their subsequent use without prescription in feed, water or treatment. Although there are major challenges in capacity for laboratories in human and animal health to conduct routine surveillance there are efforts underway supported by the development partners to improve infrastructure especially for cross border monitoring of disease outbreaks and these efforts can be enhanced to include surveillance on antimicrobial use and resistance.

The privatization of veterinary and extension services has resulted in a scenario where prevalence of animal diseases is high; poor husbandry practices are adopted; low income households do not access services; unqualified personnel administering medicine to animals and operate small unlicensed retail outlets for agricultural products and veterinary medicines.

Currently, availability of antimicrobial agents OTC without prescription is a common malpractice both in human and animal health.

In many regions of the country there is evidence of uncontrolled access, and OTC dispensing of antimicrobials without prescription and sometimes in open market to the general public. Consequently, overuse and misuse of antimicrobials is prevalent. Apart from misuse, sale of counterfeits, substandard drugs and smuggling of drugs through the porous borders were identified as challenges to controlled access to antimicrobials for humans.

1.2.3 Antimicrobial Resistance Policy in the Context of Existing Policies and Legislations

1.2.3.1 Constitution of Kenya and international obligations

The Constitution of Kenya 2010, under the 'Bill of Rights' (Articles 43(1a and c) and 46(1c)) provides for: (i) equitable, affordable and quality health care of the highest standard to all its citizens and (ii) right and fundamental freedom to "be free from hunger and to have adequate food of acceptable quality". These will be achieved through implementation of appropriate policies and programs within the relevant sectors. This Policy seeks to contribute to the achievement of the "Bill of Rights".

The Constitution upholds the principle of international law and recognizes all treaties, protocols, agreements and conventions ratified by Kenya. Chief among such supranational laws are the WTO Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures and the EAC SPS Protocol that Kenya ratified in 1995 and 2016 respectively. These govern international and regional trade in plants, animals and their products and obligate Members to apply the specified international standards.

The World Health Organization (WHO), International Health Regulations 2005 (IHR-2005), are legally binding regulations that are purposed "to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade."

AMR is a critical agenda in the international arena led by the World Health Organisation (WHO), United Nations' Food and Agriculture Organisation (FAO), World Organisation for Animal Health (OIE) and the Codex Alimentarius Commission (CAC).

1.2.3.2 Kenya Vision 2030

The Kenya Vision 2030 is the long-term development blueprint that has a vision of "a globally competitive and prosperous country with a high quality of life by the year 2030". The Social pillar of Kenya Vision 2030 provides for quality health care and the highest standard of health to Kenyans.

The blueprint recognizes the importance of agriculture towards achieving an average annual GDP growth rate of 10%. Unless tackled AMR is expected to reduce GDP growth in Kenya. Addressing AMR is expected to contribute to achieving the Vision 2030's Social Pillar on Health.

1.2.3.3 Kenya Health Policy

The Kenya Health Policy 2014-30 focuses on the two key obligations of health: contribution to economic development as envisioned in Vision 2030; and realization of fundamental human rights, including the right to health, as enshrined in the Constitution.

The national 'policy intent' of providing equitable, affordable and quality health and related services at the highest attainable standards to all its citizens. This will be achieved through six priority policy objectives: eliminating communicable diseases, reducing the burden of non-communicable diseases, reducing the burden of injuries from violence and

accidents, providing essential health services, reducing the health risk exposures and strengthening health sector collaboration. Rising trends of AMR are a risk to the realization of the objectives. This Policy gives direction on prevention and containment of this public health threat as part of the fulfilment of the provisions of the Health Policy.

1.2.3.4 Agriculture Policy

The Agriculture Policy, 2016, has provided for expansion of irrigated land, commercialization and intensification of small scale farms, research for improved crop varieties, provision of extension services and promotion of appropriate post harvest technology. The overall general thrust of the agriculture policy is to increase productivity as well as promoting food safety and prudent use of pest control products. This Policy supports the implementation of the Agricultural Policy that provides for good agricultural practices that minimize inappropriate use of antimicrobials.

1.2.3.5 Veterinary Policy

The Veterinary Policy aligns developments in the animal resource industry to the Constitution as well as to the Kenya Vision 2030, the United Nations Sustainable Development Goals and the international animal health and food safety treaties, agreements and conventions ratified by Kenya. This Policy complements the Veterinary Policy that provides for one health by addressing an institutional framework that requires multisectoral collaborations through creation of operational linkages among various sectors. The Veterinary Policy recognizes and preserves functional specialties in these institutions as it focuses on the provision where antimicrobials used in animals are prudently used to guarantee animal health and welfare and eliminate any residues in animal products to safeguard public health.

1.2.3.6 Livestock Policy

The Sessional Paper No. 2 of 2008 on the National Livestock Policy commits the government to provide for mechanisms to guarantee compliance with international standards on animal health and production inputs which includes antimicrobials. The policy mandates the Veterinary Statutory Body to ensure that the veterinary medicines and related inputs are used and handled in a manner that does not adversely affect either human or animal health. This Policy is in line with the National Livestock Policy as it provides for mechanisms for optimal use of antimicrobial agents in animal health.

1.2.3.7 National Oceans and Fisheries Policy & Aquaculture Policy

The National Oceans and Fisheries Policy 2008 provides for a coordinated framework for addressing challenges facing the fisheries. The Aquaculture Policy 2011 provides for use of Good Aquaculture Practices including prudent application and use of veterinary drugs to ensure safety of fish and fishery products intended for human consumption.

Both policies recognize measures geared towards assuring food safety and quality of fish fishery products and aquaculture inputs by preventing, minimizing or eliminating contamination, as well as improving biosecurity and creating disease free zones. This Policy complements the food safety provisions of both the National Oceans and Fisheries Policy 2008 and Aquaculture Policy 2011.

1.2.3.8 The National Infection Prevention and Control Policy

This policy provides for a clear framework for coordinated efforts to set national standards for minimizing transmission of healthcare associated infections. It provides for the establishment of a national integrated surveillance system for antimicrobial resistance. This Policy is in line with

these interventions aimed at optimizing the use of antimicrobial agents and providing data for evidence based decision making.

1.2.3.9The Kenya National Pharmaceutical Policy

Overall, the Policy focuses on strengthening the management and delivery of pharmaceutical services through relevant legislative and institutional reforms; strengthening national institutions for medicines procurement, supply, regulation and quality control; developing and appropriately managing pharmaceutical human resources; and enhancing collaboration with other sectors and with partners. These goals are complementary to the interventions proposed in the AMR policy and are geared towards improving the regulatory framework and appropriate use of antimicrobial agents.

1.2.4 Legislative environment for AMR

Antimicrobial use has been regulated mainly under the; Pharmacy and Poisons Act (Cap 244) Food, Drugs and Chemical Substances Act (Cap 254), Medical Practitioners and Dentists Act (Cap 253) Animal Diseases Act (Cap 364), Public Health Act (Cap 242), Pest Control Products Board (Cap 346), Veterinary Surgeons and Veterinary Paraprofessionals Act (Cap 366) and related professional laws as referenced in Annex 1. This Policy provides for review, updating and development of regulations to support prevention and containment of AMR.

1.2.5 AMR Policy in the Context Global Trends and International Standards

Within the tripartite collaboration on AMR, the WHO, FAO, OIE and provide the international standards to guide prevention and containment of AMR within the health and agriculture sectors.

The 68th World Health Assembly endorsed the Global Action Plan (GAP) on AMR jointly developed by the WHO, OIE and FAO. Subsequently, member states committed to develop National Action Plans (NAP) from a One Health approach. This was further augmented by endorsement for the GAP by member states during the 71st Session of the High Level UN General Assembly in September 2016. Subsequently, in May 2015, the 83rd General Assembly of the OIE adopted Resolution No. 26 Combating Antimicrobial Resistance and Promoting Prudent Use of Antimicrobial Agents in Animals and the 39th Session of FAO Conference (June 2015) also adopted resolution C 2015/28 Rev.1 on AMR. The Codex Alimentarius Commission (CAC) adopted the Code of Practice to Minimize and Contain AMR (CAC/RCP 61-2005) and developed Guidelines on Risk Analysis of Foodborne Antimicrobial Resistance (CAC/GL 77-2011).

These collaborative efforts have provided the international standards guiding prevention and containment of AMR within the health and agriculture sectors.

1.3 Scope of the Policy

This Policy covers; emergence and spread of antimicrobial resistance arising from antimicrobial treatment of infectious diseases of bacterial, viral, protozoal and fungal origin. The initial implementation of this Policy will focus on antibacterial resistance. The scope covers monitoring for resistance; antimicrobial use in public health and agriculture; and disposal of antimicrobials in the environment. The Policy targets; the public; ministries, departments and agencies; non- state actors; health professionals; veterinarians; other relevant professionals; professional associations and regulatory statutory bodies; involved in the regulation, importation, distribution, retailing, dispensing, use and disposal of antimicrobials and in research into alternatives to antimicrobials.

The Policy addresses the background of antimicrobial resistance in Kenya, the situation analysis and proposes interventions. The interventions address understanding and awareness on AMR; Knowledge and evidence base on AMR and AMU; adoption of preventive measures; prudent use of antimicrobials; regulation and monitoring of use of antimicrobials; research and investment in new antimicrobials and diagnostics and multi-sectoral coordination. In addition, the Policy provides for the legal and institutional framework for its implementation; National Action Plan; financing; monitoring and evaluation; communication strategy; and the review process.

CHAPTER TWO – RATIONALE, POLICY GOALS AND OBJECTIVES

2.1 Rationale

Antimicrobial resistance poses a challenge to the significant gains made in human and veterinary medicine that have made it possible for surgical interventions, organ transplants and treatment for common infections and diseases. AMR threatens to reverse the benefits that include socio-economic gains such as longevity, quality of life, a healthy workforce and improved productivity in food animals and plants.

Globally, it is estimated that by 2050 about 10 million people will die annually from AMR related causes and negative economic effects that may amount to GDP losses of >1% and that indirect costs affecting society may be >3 times direct health care costs.

AMR is an international health priority and Kenya has ratified the resolutions by the WHA, OIE and FAO General Assemblies on combating antimicrobial resistance globally. WHO, FAO and OIE, have committed to assisting countries to combat AMR within the context of the "One Health" approach.

Approximately, 4.5 million deaths will occur by 2050 due to AMR related causes in Sub Saharan Africa, where the burden of infectious diseases is high[5]. AMR threatens to reverse the gains made in the fight against HIV/AIDS, TB and Malaria in Kenya, where 50% of the top ten leading causes of death across all ages are infectious diseases[6].

The impact of AMR on the Agricultural Sector will have enormous negative effects on the Kenyan economy. The Sector directly contributes about 26% of the country's Gross Domestic Product (GDP) and a further 27% through manufacturing, distribution and service sectors and accounts for 65% of the total export earnings[2]. AMR threatens the sustainable growth of the

[5] O'Neill O.J., 2014: *Antimicrobial Resistance: tackling a crisis for the health and wealth of nations*. The Review on Antimicrobial Resistance.

[6] http://www.healthdata.org/kenya 2015

agricultural sector in ensuring food security and trade across different economies. Mitigating the impact of AMR is therefore a national priority.

In recognition of the need to effectively address AMR, a policy requires to be developed and implemented to strengthen existing systems and coordinate multi-sectoral actions in line with the Constitution, national policies, laws & international standards.

This multi-sectoral Policy to tackle AMR has been developed for several reasons; to protect the gains achieved over the past eighty years since the discovery of AM; mitigate current and potential negative impacts of AMR on the economy; decrease the environmental pool of resistant bacteria; limit the spread of AMR to other geographical locations (cross border or other continents) or spillover in other species; and preserve the effectiveness of current and new antimicrobial agents. Unchecked, AMR is evolving and spreading at a rate that far outstrips development of new antimicrobials.

2.2 Policy Goal

The goal of this Policy is to reduce the burden of AMR and promote prudent use of antimicrobial agents to ensure that, for as long as possible, there is continued successful treatment and prevention of microbial diseases with effective, quality assured and safe antimicrobials, accessible to all who need them.

2.3 Policy Objectives

To achieve this overall goal, five strategic objectives will guide this policy:

Objective 1: Improve awareness and understanding of antimicrobial resistance through effective communication, education and training.

Objective 2: Strengthen the knowledge and evidence base on AMR through surveillance and research.

Objective 3: Reduce the incidence of infection through effective sanitation, hygiene and infection prevention and control.

Objective 4: Optimize the use of antimicrobials in human, animal and plant health.

Objective 5: To support sustainable investment that takes into account of the needs of Kenya, and increase investment in new medicines, diagnostic tools, vaccines and other interventions.

CHAPTER THREE – CHALLENGES AND POLICY INTERVENTIONS

3.1 Policy issue: Awareness and understanding on antimicrobial resistance.

The general population is at risk of exposure to antimicrobial resistant microorganisms through human-human-animal transmission, food, the environment or other transmission routes. Where antimicrobials are available over the counter the general public procures for use either on self or animals. This is because lack of awareness on antimicrobial resistance among the service providers in human health and agriculture has contributed to the emergence and spread of AMR. Technical personnel handling antimicrobial agents have knowledge gaps and communicating the risks of AMR will be very important not only to the general public but also to policy makers and others involved in the antimicrobial supply chain including medical and veterinary practices.

Measures need to be put in place to raise awareness of antimicrobial resistance and promote behavior change through communicating the risks of emerging AMR across all sectors. Public communication programs targeting different audiences in human health, animal health and agricultural practice as well as consumers, including school children, need to be developed and financed to promote better understanding and awareness.

Policy interventions

A. The National Government will:

1. Develop and disseminate appropriate messages on AMR to suit different target groups;
2. Develop AMR curriculum for inclusion in universities, middle level institutions and schools;

B. **The National and County Governments will:**

1. Enhance multisectoral communication and provide budgetary support towards a "One Health" Communication approach to AMR.

3. Develop tools for public communication and awareness creation on AMU and importance of prevention and containment of AMR.

4. Develop and deploy effective and varied communication tools & approaches to influence multisectoral behavioral change.

C. **The County Governments will**

1. Mobilize resources for information dissemination
2. Disseminate developed AMR messages stakeholders within their areas of jurisdiction.

3.2 Policy issue: Strengthen the Knowledge and Evidence Base of Antimicrobial resistance

Knowledge on medicine supply chains, antimicrobial use, drivers of AMR including practices and behavior and its impact on all sectors is critical for addressing AMR. Lack of an integrated surveillance system and weak laboratory capacity for detection and reporting antimicrobial resistance limits the availability of evidence to support decision making. There is therefor need to initiate actions for continuous data collection alongside risk mitigation.

Surveillance data will support evidence based decision making, identification of priority areas for action and communicate the importance and impact of AMR to stakeholders and decision makers.

Policy interventions:

A. The National Government will

1. Develop and support the implementation of a National integrated AMR surveillance system.

2. Mobilize resources for implementation of the National integrated AMR surveillance strategy.
3. Support data collection, provision of feedback to stakeholders and maintenance of the national database on AMR.
4. Develop guidelines for compulsory reporting on AMU and AMR trends by all stakeholders including County Governments in line with international requirements and local legislation.

B. **The National and County governments** will build the capacity of the Laboratories to support AMR surveillance

C. The County Governments will

1. Mobilize resources to implement the surveillance strategy in their counties
2. Facilitate the transmission of data on antimicrobial resistance and consumption to the National government.
3. Disseminate AMR surveillance data to the county stakeholders.

3.3: Policy issue: Reduction of antimicrobial use through adoption of preventive measures

Hygiene; infection prevention and control are essential to limit the development and spread of antimicrobial resistant infections and multidrug-resistant bacteria. To prevent transmission of antimicrobial resistant organisms the following are core components of infectious disease prevention: prevention and control, biosecurity, sanitation, hand hygiene, food and water safety; hygiene in animal premises and farms and vaccination (where appropriate); and sustainable husbandry practices. These actions if well implemented, reduce the need for antimicrobials as well as the risk of development and spread of antimicrobial-resistant organisms.

Prophylactic use of antimicrobial in humans and animals, to prevent the infection and spread of diseases, and their use as growth promoters should be discouraged as they aid the development of AMR. Use of vaccines can

reduce infection rates and dependence on antibiotics.

Policy interventions

A. **The National Government will**

1. Review and develop guidelines for infection prevention and control (IPC); hygiene & sanitation; good agricultural and animal husbandry practices; preventive vaccinations; farm biosecurity; food and water safety; & prudent antimicrobial use.
2. Develop and/or review existing legislation to support compliance IPC guidelines.

B. **National and County Governments will:**

1. Ensure appropriate employment and deployment of appropriate technical staff to support implementation of the guidelines developed.
2. Allocate resources to support the implementation of infection prevention and control measures (without use of antimicrobials).

C. **The County Government will**

1. Support and monitor the implementation & compliance to the relevant guidelines.
2. Provide incentives for utilization of disease preventive measures and vaccines as alternatives to prophylactic antimicrobial use.

3.4 Policy issue: Prudent (optimal) use of antimicrobials

Antimicrobial agents are used in human, terrestrial and aquatic animals & plant production practices for both therapeutic and non therapeutic

purposes. Antimicrobial resistance is driven by the volume of use reflected in over- prescription and unrestricted access. This is complicated by a complex pharmaceutical system compromised by the existence of illegal medicine outlets. In regions where private professional human and agricultural services are not viable, and the government has not deployed sufficient personnel, the public has no access to technical support for appropriate antimicrobial use. Further, the inadequate utilization of laboratory diagnostic services and lack of microbiology laboratories has contributed to indiscriminate use of antimicrobials.

Non-compliance to good practices along the medicine manufacturing, supply, distribution and use chain by professionals and non-professionals is another significant contributor to the emergence of antimicrobial resistance.

Policy interventions

A. The National Government will:

1. Develop and review policies, guidelines and strategies to optimize and regulate the use of antimicrobials.
2. Review, develop and enforce legislation on prudent use of antimicrobial agents.
3. Provide for mechanisms to implement the guidelines by County Governments.
4. Ensure that professional regulatory bodies support health care provider compliance to antimicrobial use guidelines.

B. The National and County Governments will:

1. Ensure appropriate human resourcing including deployment of technical staff to support prudent use of antimicrobials.
2. Ensure that antimicrobials are manufactured, distributed, prescribed and dispensed as per developed standards and guidelines.

3. Ensure uninterrupted access to essential antimicrobial agents at all levels of care.
4. Strengthen diagnostic services for human and animal health to support prudent use of antimicrobials.

3.5 Policy issue: Capacity to regulate and monitor use of antimicrobials

The laws governing appropriate use of antimicrobials exists in Kenya. However, weak enforcement of these laws regulating the use of antimicrobial agents has posed a major challenge due to inadequate capacity and oversight to monitor compliance to regulations. The practice within the health sector is regulated under multiple laws creating the need for coordination and the structure and capacity for regulation of veterinary medicines is inadequate. This hinders the ability to effectively regulate the importation, manufacture, distribution and use of antimicrobials in both human and animal health sectors.

The laboratory capacity to undertake quality assurance of antimicrobials, routine testing of the quality and efficacy of medicines and diagnostic samples is inadequate.

Policy interventions:

A. The National Government will:

1. Review and/or develop appropriate legislation on antimicrobial use.
2. Strengthen the integrated regulatory system to ensure that antimicrobial agents are appropriately used in human and animal health
3. Strengthen the laboratory capacity for the regulatory authority to support quality assurance, including post market surveillance, for antimicrobial agents.

3.6 Policy issue: Research, development and investment in new antimicrobials and diagnostic tools.

Research is required to identify trends in AMR including the practices driving resistance in Kenya to inform appropriate interventions. In addition, there is need for investment in the discovery and development of new antimicrobials, diagnostic tools, alternative medicines and vaccines. Further information is required on economic impact assessments on health and the socioeconomic burden of AMR. Research and investment in these areas can contribute to the overall reduction in inappropriate use of antimicrobial agents.

Policy interventions:

A. **The National Government will**

1. Increase investment in research for new and existing antimicrobials, diagnostic tools, alternative medicine, vaccines and other interventions.
2. Provide an enabling environment for private sector to undertake research and development of new antimicrobials, vaccines, alternative medicine and diagnostics.
3. Collaborate with local and international research organizations to support research in antimicrobial resistance.

B. **The National and County Governments** will invest in operational research on AMR that takes into account the needs of Kenya.

3.7 Policy issue - Multi-Sectoral Coordination Mechanisms

The AMR agenda is multi-sectoral, creating the need for a holistic One Health approach bringing together the human, animal, environment and plant sectors. Currently, each sector operates under distinct mandates with weak linkages due to lack of proper coordination mechanisms.

Policy interventions

- **The National and County Governments**
    - will institutionalize mechanisms for coordination of the AMR agenda across all the relevant sectors.
    - will integrate the AMR agenda within the sectoral plans.

CHAPTER FOUR – POLICY IMPLEMENTATION FRAMEWORK

4.1 Legal Framework

Existing legislation will guide the implementation of this Policy and where necessary these will be reviewed and new ones developed to incorporate the AMR agenda.

4.2 Institutional Framework

4.2.1 Public Sector

The implementation of this Policy will be undertaken by:

4.2.1.1 National Government

a) **The Ministry responsible for Health** -will provide leadership in the Implementation of this Policy and host the multisectoral Secretariat for the AMR agenda. The MOH will provide leadership in the implementation of the AMR agenda within the Health Sector.

b) **The Ministry responsible for Agriculture, Livestock and Fisheries**.

The MALF will provide leadership in the implementation of the AMR agenda in the Livestock, Fisheries and Crop sub sectors. The MALF will be part of the AMR secretariat.

c) **The Ministry responsible for Environment** will support implementation of the AMR agenda with respect to the Environment.

d) Other Government Ministries, Departments and Agencies (MDAs). While carrying out their mandates, relevant MDAs will support specified roles in the AMR agenda.

4.2.1.2 County Governments

a) The Department responsible for Health will provide leadership in the Implementation of this Policy at the County in addition to implementation of the AMR agenda within the Health Sector.

b) The Department responsible for Veterinary Services will provide leadership in the implementation of the AMR agenda in the Livestock, Fisheries and Crop sub sectors.

c) The Department responsible for Environment will support implementation of the AMR agenda with respect to the Environment.

d) Other Departments and Agencies while carrying out their mandates will support specified roles in the AMR agenda.

4.2.1.2 AMR Coordination Mechanism

a) National Government

The Ministries responsible for Health and Livestock, Fisheries & Crops will jointly establish the multisectoral AMR Secretariat hosted at the Ministry responsible for Health to coordinate the AMR agenda. Institutions that will play leading roles in the implementation of this Policy include National and County Ministries, Departments and Agencies responsible for Health, Agriculture (Crop, Livestock and Fisheries) and parastatals that are listed in Annex 2.

The ministries responsible for health, livestock, crops and fisheries will implement this Policy and associated Strategic and Action Plans in a "One-Health" approach.

The lead ministries will establish a National Antimicrobial Stewardship Interagency Committee (NASIC). NASIC will be governed through a Steering Committee (SC) and a Technical Committee (TC).

NASIC-SC will comprise of Principal Secretaries of relevant ministries and two representatives of the Council of Governors. The NASIC-SC will be responsible for policy direction, resource mobilization, budget and work plan approvals.

NASIC-TC will comprise of Technical Directors of relevant ministries and experts. The NASIC-TC will be responsible for technical oversight, overseeing the implementation of the National Policy for AMR. It shall also ensure close coordination with other relevant stakeholders.

b) County Government

At the County Government, the lead Departments (Health and Agriculture) will establish a County Antimicrobial Stewardship Interagency Committee (CASIC). CASIC will comprise of County Executive Committee members, County Chief Officers of relevant Departments Technical County Directors and experts. The CASIC will be responsible for approving budgets and work plans, resource mobilization and implementation of the Policy at the county level.

4.2.2 Role of Private Sector

The private sector will collaborate with the government to facilitate a coordinated approach through which implementation of this Policy will be done. Private sector includes: CBOs; NGOs; cooperative societies; pharmaceutical industries; input suppliers such as feed manufacturers; food processors; development partners, professional regulatory bodies and associations.

4.2.3 Role of International Agencies

These agencies will play a significant role in resource mobilization and technical assistance towards implementation of this Policy. These include but are not limited to: WHO, FAO, OIE, EAC, IGAD, COMESA, AU-IBAR and WTO.

4.3 National Action Plan on Antimicrobial Resistance

A comprehensive National Action Plan (NAP) will be developed to implement this Policy in line with the Global Action Plan (GAP) on AMR. The NAP will be implemented in collaboration with relevant multisectoral partners.

4.4 Financing

The National and County Governments in collaboration with development partners will ensure that adequate funding is available to enable the implementation of sustainable AMR countermeasures as identified in this Policy and the National Action Plan. The budget for implementing AMR activities will be in the respective MDAs. The budget for the secretariat will be drawn from the Ministry responsible for Health. The County governments will provide budgets for the implementation of the Policy within their jurisdictions. The development partners will contribute towards meeting the budgetary costs in implementing the AMR National Action Plan.

4.5 Monitoring and Evaluation (M&E)

This Policy provides for the development of a comprehensive M& E framework. Programmed monitoring and evaluation at management and technical levels through a Monitoring and Evaluation Framework is necessary to ensure that NAP objectives are met. The M&E framework is expected to utilize the relevant provisions of the National Integrated Monitoring and Evaluation Systems (NIMES) and have clear terms of reference for relevant stakeholders in data collection and reporting at all levels. There will be an

Annual Review Report (ARR) on implementation of this Policy that will be presented to the Cabinet Secretaries responsible for Health and Agricultural subsectors.

4.6 Communication Strategy

A communication strategy is essential for creating awareness, influencing behavior change and controlling AMR. The strategy will be developed to ensure flow of information among the stakeholders: within the national government, between national and county governments, among the county governments, between the government and the private sector, farmers, the public, patients, professionals and other stakeholders.

4.7 Policy review

This Policy is a progressive document that will be reviewed as and when necessary.

ANNEXES

ANNEX 1: LAWS

1. Agriculture and Food Authority Act No. 13 of 2013
2. Animal Diseases Act, Chapter 364
3. Biosafety Act, Number 2 of 2009
4. Clinical Officers Act Cap 260
5. Crops Act, 2013
6. Dairy Industry Act, Chapter 336
7. Environment Management Coordination Act
8. Fertilizers and Animal Foodstuffs Act – 345
9. The Fisheries Management and Development Act No. 35 of 2016
10. Food, Drugs and Chemical Substances Act, Chapter 254
11. Health Records and Information Managers Act No.15 of 2016
12. Meat Control Act, Chapter 356
13. Medical lab technicians and technologists act (CAP 253 A)
14. Medical practitioners and dentists act (CAP 253)
15. Nurses Act Cap 257
16. Pest Control Products Act, Chapter 346
17. Pharmacy and Poisons Act, Chapter 244
18. Prevention of Cruelty to Animals Act, Chapter 360
19. Public Health Act, Chapter 242
20. Standards Act, Chapter 496
21. Veterinary Surgeons and Veterinary Para-professionals Act, Cap 366

ANNEX 2 IMPLEMENTING INSTITUTIONS

1. Agricultural Food Authority (AFA)
2. Clinical Officers Council
3. Kenya Agricultural and Livestock Research Organization (KALRO)
4. Kenya Dairy Board
5. Kenya Fisheries Service
6. Kenya Institute of Curriculum Development
7. Kenya Marine Fisheries Research Institute (KEMFRI)
8. Kenya Meat Commission,
9. Kenya Medical Practitioners and Dentists Board
10. Kenya Medical Research Institute
11. Kenya Medical Supplies Authority
12. Kenya Plant Health Inspectorate Services (KEPHIS)
13. Kenya Veterinary Board (KVB)
14. Kenya Veterinary Vaccines Production Institute
15. Kenya Wildlife Service (KWS)
16. Kenyatta National Hospital
17. Moi Teaching and Referral Hospital
18. National Council for Science and Technology
19. National Environmental Coordination and Management Authority (NEMA)
20. National Hospital Insurance Fund
21. National Quality Control Laboratories
22. Nursing Council of Kenya.
23. Pest Control Products Board (PCPB)
24. Pharmacy and Poisons Board (PPB)
25. Universities & Colleges

GLOSSARY

Antimicrobial Agent: Any substance of natural, semi-synthetic, or synthetic origin which at *in vivo* concentrations kills or inhibits the growth of microorganisms by interacting with a specific target

Antimicrobial Resistance (AMR): The ability of a microorganism to multiply or persist in the presence of an increased level of an antimicrobial agent relative to the susceptible counterpart of the same species.

Antibiotic: A substance often derived from microorganisms particularly moulds, with bactericidal (kill bacteria) or bacteriostatic (inhibit the growth of bacteria) properties. There are various groups which are classified according to the mechanism of action e.g beta-lactam; chemical structures e.g. tetracyclines or spectrum of activity.

Antimicrobial agent: Substance which may be natural, semi-synthetic or synthetic, which can kill or inhibit the growth of microorganisms. Eg. Antifungals, antibacterial.

Antimicrobial Stewardship (AMS): Antimicrobial stewardship is a coordinated program that promotes the appropriate use of antimicrobials (including antibiotics), reduces costs of care, improves patient outcomes, reduces microbial resistance, and decreases the spread of infections caused by multidrug-resistant organisms

Biosecurity: a strategic and integrated approach that encompasses the policy and regulatory frameworks (including instruments and activities) that analyse and manage risks in the sectors of food safety, animal life and health, and plant life and health, including associated environmental risk.

Diagnostic stewardship: coordinated intervention to improve and measure the appropriate use of microbial diagnostics to identify pathogens and guide therapeutic decision by promoting appropriate and timely selection and collection of specimens, accurate and timely testing, accurate and timely reporting of results

Infection prevention and control: A set of practices, protocols, and procedures that are put in place to prevent infections that are associated with healthcare service provision settings.

Health worker or health professionals: doctors, nurses, pharmacists, pharmacy technicians, and the community healthcare workers.

Healthcare-associated infections: Are infections that patients develop during the course of receiving healthcare treatment for other conditions.

Hygiene: conditions and practices that help to maintain health and prevent the spread of diseases for example environmental cleaning.

One Health is the integrative effort of multiple disciplines working locally, nationally, and globally to attain optimal health for people, animals, and the environment.

Surveillance: Surveillance involves collecting, managing, analysing, and reporting infections that occur. Surveillance in AMR includes data about the resistance in specific bacterial pathogens, consumption of antimicrobial agents, closely integrated with timely dissemination of results for use in planning, implementing, and evaluating the burden of AMR and for providing the necessary information for action in support of local and national strategies.