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SOUTH AFRICAN ANTIMICROBIAL RESISTANCE NATIONAL STRATEGY FRAMEWORK; A ONE HEALTH APPROACH 2018 – 2024

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I. FOREWORD BY THE MINISTER OF HEALTH AND MINISTER OF AGRICULTURE, FORESTRY AND FISHERIES

Antimicrobial resistance is a major threat to the long-term security of public health and has the potential to negatively impact our society. It is a serious and growing global health security risk, which needs to be prioritised at local and international levels.

A national response to antimicrobial resistance is required to complement the development of a global action plan, as articulated in the World Health Organisation's (WHO) resolution EB134/37 "Combating antimicrobial resistance including antibiotic resistance", adopted by the World Health Assembly in May 2014. The summarised actions required of member states include:

- Increase political awareness, engagement and leadership
- Strengthen infection prevention and control
- Strengthen international collaboration
- Strengthen overall pharmaceutical management systems, including regulatory systems and supply chain mechanisms, as well as laboratory infrastructure
- Monitor the extent of antimicrobial resistance
- Encourage and support research and development
- Promote responsible use of antimicrobials
- Encourage the development of novel diagnostics and antimicrobial drugs
- Develop an antimicrobial resistance surveillance system for inpatients in hospitals, for outpatients in all other health care settings and the community, and for animals and non-human usage of antimicrobials
- Develop a national plan with accountability and civil society engagement.

In animal health, the International Committee of the World Organisation for Animal Health (OIE) published a set of guideline documents in 2003 for all OIE Member Countries relating to the public health risks of antimicrobial resistance, originating from the use of antimicrobial drugs in veterinary medicine. These guidelines were used by the Medicines Committee of the South African Veterinary Association together with the Faculty of Veterinary Science, University of Pretoria to develop technical guidelines for the responsible and appropriate use of antimicrobials in veterinary medicine in South Africa. These guidance documents underpin efforts that have been made during the past decade to create and strengthen awareness within the veterinary profession of the emerging threat of antimicrobial resistance, and their implementation needs to be strengthened through legislative and policy reform in the animal health sector. In March 2016, the Department of Agriculture, Forestry and Fisheries published the South African Veterinary Strategy 2016-2026 which sets out how veterinary services will improve the health and welfare of animals and ensure that food and products produced from animals are safe for consumption by humans. The document acknowledges the key new challenge of antimicrobial resistance which is a global risk to animal and public health.

The National Department of Health and Department of Agriculture, Forestry and Fisheries have collectively engaged to determine the key interventions that will form the basis for this strategy taking into account the recommendations from the WHO and OIE.

The development and implementation of a National Antimicrobial Resistance Strategy Framework that complements international efforts is a major step towards containment of the growing threat of antimicrobial resistance in human and animal health. Global partnerships need to be strengthened because the responsibility for reducing resistance is a shared one. This responsibility is not only limited to the health care sector, but calls for collaborative action in all sectors - human, animal and agriculture.

The National Antimicrobial Resistance Strategy Framework will affect South Africa's response to this looming threat. We already have the tools and expertise to make a difference, now all we need is to work together toward a better future.

Signature of Minister Of Health
DR A MOTSOLEDI, MP
MINISTER OF HEALTH

Signature of Minister DAFF
MR S ZOKWANA, MP
MINISTER OF AGRICULTURE, FORESTRY AND FISHERIES

II. PREAMBLE BY THE DIRECTOR GENERAL OF HEALTH

Antimicrobial resistance is a major global public health crisis. In the case of bacterial infections, decades-long overuse of antibiotics has resulted in a tipping point, where the world finds itself on the brink of a 'post-antibiotic' era and we will lose the benefits of these medicines entirely.

The discovery of penicillin in 1928 heralded a revolution in the treatment of infections. But even at that time, Alexander Fleming warned about driving selection of resistance through inappropriate use. Since 1987, no new class of antibiotics has been discovered. The alarming trend in the rise of resistance to existing antibiotics and the slow-down in the development of new antibiotics will lead to the catastrophic consequence of not being able to treat common infections effectively. Conditions that were previously managed with first line agents are becoming harder to treat because infections have become more severe, often requiring prolonged treatment, as is the case with drug-resistant tuberculosis. This also leads to an increase in the cost of healthcare because of the need for more expensive second or third line antimicrobial agents for a prolonged duration, increased hospitalisation and length of stay of those hospitalised, and importantly, a reduced quality of life.

In 2013, the identification of a *Klebsiella pneumoniae* resistant to all available antibiotics exemplified the most extreme case of multi-drug resistant bacterial infection yet documented in South Africa. A potentially stark future awaits us, where patients may die of untreatable bacterial infections, which were previously easily managed.

This National Antimicrobial Resistance Strategy Framework has been developed as a framework for managing antimicrobial resistance, to limit further increases in resistant microbial infections, and improve patient outcomes. In this policy, priority is given to resistance of bacterial infections other than tuberculosis to antibiotics, as structures to address resistance in tuberculosis as well as resistance in HIV, already exist in the National Department of Health. However, many of the interventions included in the strategy apply equally to all antimicrobials.

**MS MP MATSOSO
DIRECTOR-GENERAL: HEALTH**

III. PREAMBLE BY THE DIRECTOR GENERAL OF AGRICULTURE, FORESTRY AND FISHERIES

The emergence of antimicrobial resistance is an increasing threat to global health. In livestock husbandry, the use of antimicrobials that are critically important for human and veterinary medicine, as defined by the WHO and OIE, should be reduced and further guided by scientific risk assessments. The use of antimicrobials needs to be targeted to the treatment of specific cases of disease in response to therapeutic reasons authorised by veterinarians or other person trained and authorised in accordance with national legislation.

In order to globally strengthen antimicrobial resistance controls, we propose regular engagement and exchange of views between relevant authorities from the fields of human health, animal health, agriculture and environment. This should be carried out as far as possible within existing for and in coordination with the existing partnerships.

This National AMR Strategy represents the interdepartmental collaboration from a One-Health perspective which highlights antimicrobial resistance surveillance in people, animals and the environment at all levels of the agriculture food chain. The Department of Agriculture, Forestry and Fisheries is committed to working together with the Department of Health in combating the challenges of AMR in South Africa and globally.

**MR RM RAMASODI
ACTING DIRECTOR-GENERAL: AGRICULTURE, FORESTRY AND FISHERIES**

IV. ABBREVIATIONS

AFA	Antimicrobial Feed Additive
AMR	Antimicrobial Resistance
AMS	Antimicrobial Stewardship
DAFF	Department of Agriculture, Forestry and Fisheries
DBE	Department of Basic Education
DEA	Department of Environmental Affairs
FAO	Food and Agriculture Organisation of the United Nations
HAI	Hospital Acquired Infection
HSS	Health Systems Strengthening
IPC	Infection Prevention and Control
MDR	Multi-Drug Resistance
NDoH	National Department of Health
OIE	World Organisation for Animal Health
SAHPRA	South African Health Products Regulatory Authority
WHO	World Health Organisation

V. DEFINITIONS

Antibiotic: any of a large group of chemical substances, such as penicillin, having the capacity to inhibit the growth of, or to destroy bacteria and other microorganisms, used chiefly in the treatment of infectious diseases.

Antimicrobial: an agent such as a medicine that destroys or inhibits the growth of a microorganism.

Antimicrobial resistance (AMR): the ability of a microorganism to withstand treatment with an antimicrobial medicine.

Antimicrobial stewardship (AMS): a systematic approach to optimising the appropriate use of all antimicrobials to improve patient outcome and limit emergence of resistant pathogens whilst ensuring patient safety.

Biosecurity: Represents a set of preventative procedures and measures that are designed to protect a given population (human or animal) against harmful biological organisms and products.

Compounding – is the manipulation of available medicines or pure chemical substances to obtain a new dosage form. In the case of registered medicines this includes any product manipulation that results in alternate instructions other than that already provided on the approved medicine packaging.

Diagnostic stewardship - is defined as the “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.”¹

Equity: is impartial or just treatment, requiring that similar cases be treated in similar ways.

Essential medicines: are those that satisfy the priority health care needs of the population. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford.²

Evidence-based medicine: is a process of independent and objective decision making based on consideration of objective data with integration of best research evidence (external) with clinical expertise (internal) and patient values.

Governance: is the strengthening of organisational structures for appropriate decision making, authority and oversight.

Good governance: is characterised by equity, transparency, evidence-based medicine, accountability, participation, rule of law and responsiveness.

Growth promotion: refers to improved feed utilization and growth rate and is obtained through an inhibitory effect on intestinal microbes when antimicrobials are added to the feed or water of food-producing animals

Medicine management system: is a set of practices and policies related to the selection, procurement, distribution and use of medicines.

Rational medicine use: requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.³

Transparency: means that the degree of disclosure to reach agreements, dealings, practices and transactions is open to verification.

VI. INTRODUCTION

Antibiotics play a vital role in the management of bacterial infections, reducing morbidity and preventing mortality. They are estimated to increase life expectancy by 20 years. However, the extensive use of antibiotics in animal and human health, agricultural, and environmental sectors has resulted in drug resistance that threatens to reverse the life-saving power of these medicines. A tipping point has been reached for the international community, where we find ourselves entering a “post-antibiotic era”. In South Africa, the identification and publication of the first untreatable, pan-resistant *Klebsiella pneumoniae* from the urine of a patient admitted for cardiac surgery⁴, and the emergence of colistin resistant genes in poultry and humans represents the extreme end of the spectrum of increasingly common multi-drug resistant (MDR) bacterial infections in this country.

AMR or the ability of a microorganism to withstand treatment with an antimicrobial medicine, is a significant and multifaceted public health problem and a direct threat to human and animal health, food security and the continued use of available antimicrobials. The societal and financial costs of treating antimicrobial resistant infections in humans and animals will place a significant human and economic burden on society and compromise food security.

Sixty percent of the human pathogens come originally from animals and therefore it is clear that AMR poses a serious global threat to both animal and human disease treatment. From an animal health perspective antimicrobial agents are essential tools for protecting animal health and welfare, and also contribute to satisfying the increasing world demand for safe food of animal origin,

¹ WHO, Draft Implementation Manual On Global Surveillance of Antimicrobial Resistance (GLASS) June 2015

²http://www.who.int/medicines/services/essmedicines_def/en/ (accessed 13/02/2014)

³http://www.who.int/medicines/areas/rational_use/en/ (accessed 11/03/2014)

⁴Brink AJ et al. J ClinMicrobiol.2013 Jan;51(1):369-72. doi: 10.1128/JCM.02234-12. Epub 2012 Nov 14

The drivers of antibiotic resistance include:

1. **The total volume of antibiotics used by humans and in animals:** International estimates suggest that half of all antibiotics prescribed in humans are unnecessary, either as no infection exists, the infection is not caused by a bacterium, or antibiotics are prescribed for too long a duration. Approximately, 80% of all antibiotics used globally are for animal health, agriculture and aquaculture to prevent or treat infection, or for growth promotion in the feed of animals.
2. **Reliance on broad-spectrum antibiotics,** which have activity against a wide range of different bacteria will select out a greater range of resistant bacterial populations as opposed to narrow-spectrum antibiotics, which target the specific bacteria causing infection.
3. **Poor infection control practices leading to the acquisition and spread of HAI:** Hospitalised patients are at high risk of developing a MDR bacterial infection, as they are often immune-compromised, may have MDR bacteria transferred to them as a result of poor hand hygiene practice by health care professionals, and may have MDR bacteria introduced into the body as a result of invasive procedures and devices.
4. **Lack of veterinary health professionals, weak regulations and enforcement mechanisms** to oversee antimicrobial use and control of its appropriate application in animals.

A return to appropriate, targeted antimicrobial use in humans, animals and the environment is critical to conserve the antimicrobial armamentarium.

As awareness of the current status of AMR in South Africa increased, AMS interventions were developed and implemented at the institutional level to begin to address the growing problem. However, they were confronted with the weaknesses of existing control systems and challenges in scaling up interventions. The AMR Background Report and Situation Analysis; Antibiotic use and resistance in South Africa as published in 2011 in the South African Medical Journal takes stock of these interventions and describes the strengths and weaknesses of the health system in light of the AMR situation in the country.

This National AMR Strategy Framework outlines key strategic objectives to slow the development and spread of AMR, and improve patient outcomes, animal health and food production through better use of antimicrobials. Whilst acknowledging the importance of AMR in tuberculosis (TB), HIV, and malaria, the immediate and unmet need is to combat increasing levels of resistance in bacteria other than TB in South Africa, which is therefore the main focus of this document. Antibacterials and antifungals in animal health are the key focus of this document. The National AMR Strategy Framework, supported by comprehensive guidance documents on AMR in both the human and animal health sectors will guide implementation efforts.

VII. LEGISLATIVE FRAMEWORK

- a. The **Constitution of South Africa (Constitution)** guides the substantive content of all laws and policies through its Bill of Rights. The Constitution provides for health policy and practices that respond to the needs of South Africans. In terms of Chapter 2, Section 27 of the Constitution access to health care in itself is a basic human right. All reasonable measures must be taken to ensure that this right is protected, promoted, and fulfilled within the limits of available resources.
- b. The **National Health Act (Act 61 of 2003)** provides the framework for a structured uniform health system within South Africa. The Act specifically provides for the establishment of “a system of co-operative governance and management of health services, within national guidelines, norms and standards, in which each province, municipality and health district must address questions of health policy and delivery of quality health care services”.
- c. The **Medicines and Related Substances Act (Act 101 of 1965)**, as amended, provides the legislative framework to ensure that medicines are safe, efficacious and of good quality. It also provides for control of veterinary medicines in such a way as to ensure that they are produced, distributed and used without compromising human and animal health. Antimicrobials intended for use in animals and registered under Act 101 can only be administered or prescribed by a veterinarian. This act also makes provision for compounding of medicines for use in animals.

- d. **Pharmacy Act (Act 53 of 1974)** provides for education and training requirements for pharmacists and pharmacy assistants, regulates the registration and ownership of pharmacies and the control of good pharmacy practices by pharmacists including dispensing of medicines control.
- e. **The Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act (Act 36 of 1947)** provides for the registration of quality assured, safe and effective remedies. The Act is administered by the Minister of Agriculture, who appoints a Registrar. The Act controls imports, registration of new remedies, sales, applications and supply of these substances. Animal feeds which include medicated feeds, milled substances, vitamins, minerals, herbs, bone-meal products and licks are regulated by this Act. Excluded from control are straw, chaff, unmilled hay, silage, grain and products milled by farmers for their own use. Act 36 also regulates the use of antimicrobials for growth promotion and the purchase of antimicrobials over the counter (OTC) by the lay public (chiefly farmers). The DAFF has a responsibility to ensure that farmers have access to veterinary medicines for disease control and improved food production and to safeguard the population by monitoring residues (including antibiotics) in products of food-producing animals. It makes provision for extra label use of remedies by veterinarians.
- f. The **Public Finance Management Act (Act 1 of 1999)** ensures that all revenue, expenditure, assets and liabilities of all levels of governments are managed efficiently and effectively and provides for the responsibilities of persons entrusted with financial management to support, among others, sustainable access to health care and medicines.
- g. The **National Drug Policy (NDP)** health objectives are to ensure the availability and accessibility of essential medicines to all citizens, to ensure the safety, efficacy and quality of medicines, to promote the rational use of medicines by prescribers, dispensers and patients through provision of the necessary training, education and information and to promote the concept of individual responsibility for health, preventive care and informed decision making.
- h. **Foodstuffs, Cosmetics and Disinfectants Act, 1972** is administered by the NDoH, enforced by local authorities, whilst provincial health authorities conduct import control. It forbids the sale of foods that are harmful to health, protects consumers from exploitation by false or misleading claims, and provides consumers with information for making informed choices according to individual needs and wishes. The act sets the minimum residue limits for antimicrobials and all chemicals in animal and animal products.
- i. **Meat Safety Act 2000** provides for measures to promote meat safety and the safety of animal products; establishes and maintains essential national standards in respect of abattoirs; regulates the importation and exportation of meat and establishes meat safety schemes.
- j. **The Health Profession Act (Act 56 of 1974)** provides for control over the education, training and registration for and practicing of health professions registered under this Act.
- k. **The Veterinary and Para-Veterinary Professions Act (Act 19 of 1982)**. The South African Veterinary Council seeks, through the statutes of the Veterinary and Para-veterinary Professions Act, 1982 to serve the interests of the people of South Africa by:
 - Protecting and representing the interests of the veterinary and para-veterinary professions;
 - Regulating the professional conduct of the veterinary and para-veterinary professions; and
 - Setting and monitoring standards of both education and practice for the veterinary and para-veterinary professions.

The Rules of the Act makes provision for the compounding and or dispensing of any medicine which is prescribed by a veterinarian for use in the treatment of an animal which is under his or her professional care and off label use by veterinarians.

l. **National Environmental Management: Waste Act, (Act 59 of 2008)** aims to protect health and the environment by providing reasonable measures for the prevention of pollution and ecological degradation. It provides for national norms and standards for regulating the management of waste by all spheres of government and for specific waste management measures, the licensing and control of waste management activities.

m. **National Environmental Health Norms And Standards For Premises And Acceptable Monitoring Standards For Environmental Health Practitioners as part of The National Health Act, 2003 (Act No. 61 of 2003)** includes Norms and Standards for food safety for food handlers and food production

premises, sanitation services, water quality monitoring, health surveillance of premises including abattoirs and food processing premises, waste management and communicable diseases control.

- n. **Animal Diseases Act (Act No. 35 of 1984)** provides for the control of animal diseases and parasites, and for measures to promote animal health.
- o. **Animals Protection Act (Act No. 71 of 1962)** makes provision for the protection of animals through the procurement and rendering of medical treatment or attention for animals in need, whether through disease, injury, delivery of young or any other cause.

VIII. STRATEGIC OBJECTIVES AND ENABLERS OF THE NATIONAL ANTIMICROBIAL RESISTANCE STRATEGY FRAMEWORK

1. Purpose of the strategy

The purpose of the National AMR Strategy Framework is to provide a structure for managing AMR among humans and animals to limit further increases in resistant microbial infections, and improve the health of the population.

2. Goals of the strategy

The goals of the strategy are:

- to define the principles and short to medium term interventions needed to preserve the effectiveness of antimicrobials for future generations;
- to improve the appropriate use of antibiotics in human and animal health to limit the transfer of antimicrobial residues and AMR organisms in the food chain;
- to improve the effective management of antibiotic resistant organisms and prevent their transmission;
- to create an enabling environment for the successful and sustainable implementation of the strategic objectives.

3. Strategic framework

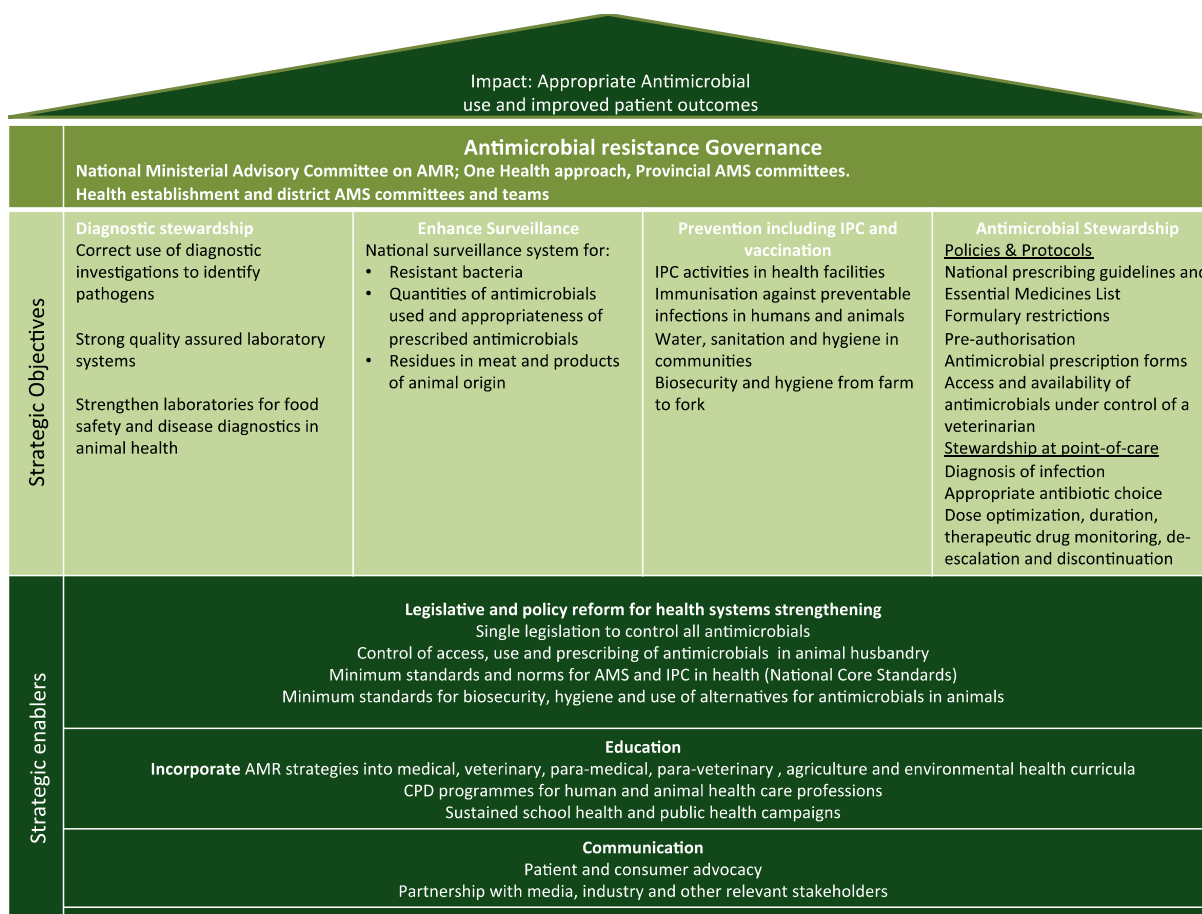
The strategic framework consists of five (5) strategic objectives that are underpinned by 4 key enablers as described in figure 1. The strategic objectives are:

- Strategic objective 1: Strengthen, coordinate and institutionalise interdisciplinary and intersectoral efforts** through national and provincial One Health governance structures which encompasses human, animal, and environmental health experts.
- Strategic objective 2: Diagnostic Stewardship** to improve the appropriate use of diagnostic investigations to identify pathogens and guide patient and animal treatment and antimicrobial management whilst strengthening quality laboratory systems for the detection of disease.
- Strategic objective 3: Optimise surveillance and early detection of AMR and antimicrobial use** to enable reporting of local, regional, and national resistance patterns to optimise empiric and targeted antibiotic choice.
- Strategic objective 4: Enhance infection prevention and control and biosecurity** to prevent the spread of resistant microbes to patients in healthcare settings and between animals, farms and countries. Reduced use of antimicrobials by disease prevention and community measures include wide-reaching vaccination programmes, improvements in water and sanitation, and improved biosafety.
- Strategic objective 5: Promote appropriate use of antimicrobials in human and animal health** through AMS practices and controlled access to antimicrobials to ensure availability.

The key enablers of these strategic objectives are:

- Legislative and policy reform for health systems strengthening** to support the quality of antimicrobials in the country and to harmonise existing legislation to enable control over antimicrobials through a single Act;
- Education** of all levels of health providers in human health, animal health, agriculture and industry in the critical concepts of AMS, infection control, infectious diseases, microbiology and pharmacology.
- Communication** to educate the public, create awareness and enhance patient and consumer advocacy of the dangers of inappropriate antimicrobial use and residues in products of animal origin and the importance of infection prevention interventions that are available to South Africa's population.
- Research** into novel diagnostics including point of care testing, understanding antimicrobial prescribing and use behaviours and how to change these practices, clinical trials of treatment duration, antimicrobial consumption, and new antimicrobials.

Figure 1: Strategic framework for the National AMR Strategy



IX. STRATEGIC OBJECTIVES OF THE NATIONAL ANTIMICROBIAL RESISTANCE STRATEGY FRAMEWORK

1. Strategic objective 1: Strengthen, coordinate and institutionalise interdisciplinary and intersectoral efforts

Sub-objective 1.1: Establish an interdisciplinary National Advisory Committee

A multi-disciplinary intersectoral Ministerial Advisory Committee on AMR (MAC-AMR) is to be established, funded and mandated to coordinate intersectoral efforts nationally, provide advocacy and awareness as well as monitoring and evaluation of the implementation of this strategy framework within the provinces and health facilities and production animal farms in the country. The NDoH is primarily responsible for setting the AMR strategy, vision, mission and directing the country towards a specific outcome. It is also the key stakeholder to ensure a “One Health” approach is followed for this strategy by constituting the intersectoral governance structure. MAC-AMR will be positioned to report to the Minister of Health, within the NDoH, where leadership can be provided to influence policy development and implementation. DAFF is the key partner with the NDoH in ensuring a collaborative, integrated approach to animal and human AMR interventions. It will promote surveillance in the agricultural sector specifically in livestock for AMR and align the AMR Strategy Framework with the South African Veterinary Strategy and DAFF’s policy development processes

The role of the MAC-AMR is to:

- Advise the ministers of DAFF and NDoH on the appropriate approach for the country to improve antimicrobial use (focusing on antibiotics) to reduce resistance in humans, animals and the environment;
- Advise the Ministers on how to enhance national surveillance and reporting systems for AMR in the human health and agricultural sectors;
- Set minimum standards of activities or interventions that are to be implemented by the institutions/health establishments and determine the monitoring and evaluation system to track outcomes and impact;
- Define improvements in prevention strategies focusing on IPC, enhanced vaccination programmes, and improved biosafety.
- Advise the Ministers on appropriate communication messages for public awareness campaigns and health science professional education strategies on AMR.

The following stakeholders will be represented in or consulted by the MAC-AMR: public and private sectors, academia and universities from both human and animal health, as well as role players from other Departments such as DAFF, Trade and Industry (DTI), Science and Technology (DST) and Education (DE). Additional stakeholders include relevant clinical societies, laboratory networks, the pharmaceutical industry, military, medical aids, legal services, diagnostics companies and civil society. Existing committees involved with HIV, TB and malaria drug resistance should also form part of the MAC-AMR.

Sub-objective 1.2: Establish governance structures at operational level: Provinces, Districts, health establishments and veterinary services.

Provinces are responsible for taking the strategic objectives and standards set at National level and adapting them to suit their operational model and existing health and veterinary services operational and governance structures. The Head of Health will have an oversight role of this governance structure and will focus on establishing the strong ties needed to be developed with the veterinary services, environment, sanitation and water departments as part of the National Development Plan in each province. The control of AMR in animal husbandry and zoonotic disease in the provinces falls under the leadership of the Provincial Directors of Veterinary Services in each province.

The District Health Management Office (DHMO) and its associated sub-district management structures are primarily responsible for the coordination and planning of health services in the associated district hospital, community and primary healthcare clinics within that district and sub-district. Districts are at the forefront of the community and therefore will have an even larger responsibility for public health awareness and education activities, targeting the specific behaviours of concern for AMR in each community as well as implementing awareness relating to food safety. The DHMO also collaborates and works closely with other governmental sectors such as water and sanitation; environmental services; and waste management services at municipalities and these departments are integral to the One Health approach of AMR especially at this community level and formalised through the Integrated and District Development Plans.

Health establishments are fundamental drivers of the activities that will impact on AMR in human health. They will need to identify how the proposed management structures will fit into already existing oversight structures, how they can adapt their operational processes to improve management of AMR and how they can strengthen already existing programmes such as IPC and the Expanded Programme on Immunisation (EPI) to support the objectives of reducing the burden of infections and preventing the spread thereof. They also have a fundamental role in educating the patients, caregivers, community, healthcare providers and health workers to change their behaviours to prevent infections, prevent their spread and ensure the appropriate use of antimicrobials.

Animal health technicians are the extension officers in the field to liaise with the farmers and advise on appropriate responsible use of antimicrobials and AMR. In the future, their capacity to improve access to antimicrobials will need to be expanded in order to assist with AMR control at the farm level.

2. Strategic objective 2: Improve the appropriate use of diagnostic investigations to identify pathogens, guide patient and animal management and ensure good quality laboratory systems

Diagnostic stewardship extends from the patient or animal's side into the laboratory and relies on the skills, expertise, and capacity of the laboratory and its staff to accurately test and report on specimens it receives to guide treatment and active management of infections by the health and animal health professionals.

Focus will be on providing timely microbiological data to deliver safer and more effective and efficient treatment; and accurate and representative AMR surveillance data to inform treatment guidelines, and AMR control strategies.

In human health the National Health Laboratory Service and private laboratories will ensure quality management systems to provide consistent diagnostic standards. Optimising the use of diagnostic tests to support AMS through the use of clinical algorithms to guide prescribers on optimal use of diagnostic tests will be incorporated into clinical algorithms to management of infection in humans and animals. In the animal health sector, these objectives are partly driven by the intensive animal industries and partly by private diagnostic laboratories who serve the broader veterinary profession.

3. Strategic Objective 3: Optimise surveillance and early detection of AMR

Sub-objective 3.1: Strengthen surveillance of local and national resistance patterns and antimicrobial use

AMR surveillance encompasses the on-going, systematic collection, analysis and interpretation of AMR, antimicrobial use, medicine quality, and antimicrobial residues in food products of animal origin to assist in the planning, implementation and evaluation of AMR interventions both nationally and locally.

The existing AMR national surveillance system is to be strengthened through sharing of data between laboratories to improve understanding of trends and resistance patterns across the country in both animal and human health. This will be coordinated through a central national body which can warehouse all laboratory surveillance data into a central repository from which combined AMR reporting on AMR can occur. Surveillance data will be used, where possible, to inform policies such as Standard Treatment Guidelines (STGs) and Essential Medicines List (EML), food safety and animal health treatment guidelines.

A system to combine clinical and laboratory data for enhanced surveillance will also be investigated and implemented, improving the ability to distinguish community and hospital acquired infections and their causes.

Additional sources of antimicrobial use data will be defined to increase our understanding of national antibiotic use in animals and humans.

In animal health, the re-introduction of a national longitudinal antimicrobial surveillance programme and reporting of resistance rates in food-producing and companion animals from public and private laboratories will be developed in partnership with DAFF. This will include a system to monitor antimicrobial use and circulation in the country as well as in different livestock sectors. The system to incorporate laboratory data on residue and clinical testing with antimicrobial usage will be implemented for targeted AMR surveillance.

The National Chemical Residue Monitoring Programme for food products of animal origin is coordinated and funded by DAFF and has been in operation for many years. Non-compliance to existing legislation regarding the chemical residues in food products of animal origin is beyond the scope of this document.

Sub-objective 3.2: Develop early warning systems of sentinel organisms and outbreaks

The central national body shall develop an early warning reporting system for sentinel MDR organisms that will assist in instituting appropriate interventions to effectively contain resistance or outbreaks. This will be linked to the Notifiable Medical Conditions regulations and reporting processes.

Controlled and Notifiable Diseases including zoonotic disease which impact human health are already reported to Directorate of Animal Health within DAFF by veterinarians and veterinary laboratories and published to the public monthly. This will be integrated within the One Health surveillance system.

Sub-objective 3.3 Participation in international databases on AMR and antimicrobial use

Share South African data on AMR and antimicrobial use with WHO Global Surveillance of Antimicrobial Resistance (GLASS) and OIE databases to add to global knowledge on AMR. In animal health, surveillance

will focus on three categories of bacteria, namely indicator/commensal organisms, zoonotic organisms and selected veterinary pathogens to aid in the early recognition of multi-drug resistant bacteria.

4. Strategic objective 4: Enhance Infection Prevention and Control

Sub-objective 4.1: Prevent new infections: Vaccination and WaSH

Prevention of infection through wide-reaching vaccination programmes thereby preventing the need for antibiotic use is a key AMR prevention strategy. This will be implemented through primary prevention and promotion activities such as vaccination and awareness around its importance within the public District Health System and private health systems. In animal health this will be implemented through primary animal health care programmes facilitated through animal health technicians and Compulsory Community Service veterinarians.

Access to effective, safe, community level water, sanitation and hygiene (WaSH) services are a critical part of ensuring good hygiene in the community and reduction in the spread of diseases between humans and between animals and humans. These include clean, safe water supplies, hand hygiene, food preparation safety and good sanitation measures. Many aspects of this programme are dealt with under the Community-led WaSH programmes, within the Integrated School Health Program and directed by community engagement of Community Healthcare Workers which should to be augmented to include AMR.

Sub-objective 4.2: Prevent and control the spread of resistant microorganisms in humans and health institutions.

IPC in all health care facilities through effective IPC practices and hand hygiene is a core component of overall quality improvement⁵. Controlling the spread of resistant microbes to patients and the workforce involves rapid identification and isolation of patients with resistant organisms, access to personal protective equipment, and most importantly, improvement in hand hygiene. The multi-modal WHO intervention 'Five Moments for Hand Hygiene' will be adopted in all South African healthcare facilities as the gold standard for hand hygiene and the implementation of sustained campaigns.

A key enabler to effective infection control includes sufficient, suitably qualified and competent IPC practitioners with defined core skills and responsibilities for supporting the implementation of control measures in the facility as well as access to basic supplies and equipment needed to perform hand hygiene.

Sub-objective 4.3: Biosecurity and hygiene from farm to retail levels

Biosecurity in animal health is a core component of the prevention and control of the spread of resistant microorganisms in animal husbandry. This is more relevant for large scale farms although small scale farmers will also benefit from adapting these components. Guidelines are already available through farmer interest groups and veterinary societies and these need to be standardised and recommended for implementation in animal husbandry by a central governance body such as the South Africa Veterinary Council.

The monitoring of hygiene and sanitation systems at abattoirs and food processing establishments is legislated by DAFF and NDOH and is facilitated through Veterinary Public Health Officials and Environmental Health Practitioners. The prevention of new infections through handling of contaminated food products by food handlers and consumers must be effected through the hygiene systems at abattoirs and food processing establishments.

Sub-objective 4.4: Environmental Health and Water Quality monitoring

Ensuring the environmental health policies, Norms and Standards are implemented is the function of the Environmental Health Directorate of the NDoH that is focused on monitoring and controlling environmental health activities as executed by local municipalities. This includes food control, water quality monitoring, waste management and general hygiene monitoring and control of communicable diseases. This control system will include:

⁵ WHO, November 2016, Guidelines on Core Components of Infection Prevention and Control Programmes at the National and Acute Health Care Facility Level

- monitoring water quality by performing microbiological, physical and chemical tests for fitness for human consumption through a sampling process;
- monitoring the availability and accessibility of domestic water supply and sanitation services for protection of public health in order to implement effective hand hygiene practices in the community;
- waterborne and sanitation related disease surveillance.

In addition the Environmental Health Directorate is responsible for health and hygiene awareness education and promotion to communities as it relates to water and sanitation supply and use. A key focus area will be the provision of hand hygiene awareness focusing on 3 core components namely:

- focusing on creation of an enabling environment for washing hands with soap;
- ensuring increased knowledge on the benefits of hand hygiene with soap and on the link between poor hygiene practices and disease; and
- behaviour change by building on the key drivers and motivators in order to build and sustain the habit of hand washing with soap in the community.

5. Strategic objective 5: Promote appropriate use of antimicrobials in humans and animals

Sub-objective 5.1: Ensure access to safe, effective and affordable antimicrobials

The availability of antimicrobials according to the national STGs and EML needs to be sustainable. Robust regulatory and medicine management systems, including procurement, distribution and dispensing systems are needed to support regulated access to safe, effective and affordable antimicrobials.

The quality of medicines will be strengthened through the use of laboratory systems to monitor quality assays and pharmacovigilance reporting systems monitored by regulators such as the SAHPRA and should include veterinary medicines.

Access and availability to farmers of certain key antimicrobials under control of a veterinarian or animal health technician is needed to maintain livestock production and animal welfare. All antimicrobials for animal use should be registered under a single Act. Those that are critical to animals must be included in either Schedule 0 or Schedule 1 of this Act to allow access by rural farming communities through veterinarians or other authorised persons such as veterinary technicians. Veterinarian oversight of the use of antimicrobials in food producing animals will limit the unrestricted supply through farmer's cooperatives and general dealers and improve control of antimicrobials.

Consideration will also be given when registering animal antimicrobials which are on the WHO list *critically important* in humans so that more stringent control measures are put in place as part of registration.

The gut microbiota play a crucial role in digestion. Imbalances of gut flora negatively affect animal performance and welfare. Although producers constantly strive to avoid conditions that adversely affect gut health, in practice this is not always achievable and the use of antimicrobial growth promoters (AGPs) may be required. Where the use of these products is required, narrow spectrum antimicrobials that are not of shared use in human medicine or can impact on bacterial resistance in humans, shall be used. The AGPs that are currently registered under the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act (Act 36 of 1947) must be reviewed by means of risk assessments to continuing with them as growth promoters.

Sub-objective 5.2: Institutionalise antimicrobial stewardship in human health

Antimicrobial stewardship (AMS), while imperative for every individual prescriber, is often a multidisciplinary team approach in health institutions and districts.

AMS can help correct inappropriate use through protocols, structures and interventions including but not restricted to:

1. AMS Committee or structure to function in every Health Establishment and district aligned within the overarching clinical leadership functions.
2. AMS Teams in every institution to actively oversee appropriate prescribing and optimise antimicrobial use. Composition of an AMS team will vary depending on setting and availability of expertise. A

prescribing physician and pharmacist are the ideal core members of an AMS team. Outreach and support by experts may be sought to advise and train teams.

3. Provision, use and monitoring of protocols such as formulary restrictions, pre-authorisation of antimicrobials, monitoring the use of national prescribing guidelines such as the STGs and EML, and development of local treatment guidelines based on facility resistance data.
4. Expenditure on antimicrobials and laboratory testing is monitored and controlled without adversely impacting quality of care.

Sub-objective 5.3: Ensure antimicrobial stewardship in animal health

DAFF has adopted the OIE standards included in the *Terrestrial Animal Health Code* and *Aquatic Animal Health Code* (the *Aquatic Code*), as well as in the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual*). The OIE Codes also provide recommendations on risk assessment for AMR arising from the use of antimicrobials in animals.

The South African Veterinary Association alongside animal agriculture and the food animal producer associations will develop and update species-specific responsible use guidelines based on the OIE Codes, surveillance data of the disease burden of organisms in each species. Antimicrobials should be selected based on activity against a known pathogen and used at the correct dose and route for the correct period of time to avoid the development of resistance. The guidelines will also cover the type of documentation that should be kept and by whom it should be kept to ensure traceability.

Guidelines will include the use of alternatives to antimicrobials such as in feed enzymes, prebiotics, probiotics and competitive exclusion products once these have been researched for their benefits.

At a country level, risk assessments might be appropriately conducted to evaluate the effectiveness of efforts to ensure responsible use and mitigation strategies (for example, by identifying changes in veterinary prescribing practices) and to indicate where change of antimicrobial usage practices needs to occur.

6. Strategic enabler 1: Legislative and policy reform for health systems strengthening

AMS interventions at facility level are to be incorporated as standards within the National Core Standards⁶ and prescribed as regulated standards that accompany the National Health Act and the promulgation of the Office of Health Standards Compliance (OHSC). This will see inspectors of the OHSC assessing all Health Establishments in the country for their compliance with the basic minimum requirements for the effective implementation of the strategic objectives of this National AMR Strategy Framework.

Current legislation and national guidelines regarding health care facility infrastructure to be updated to include provision for core infection control infrastructure requirements and facilities for improved hand hygiene practice.

Certain legislations need to be changed to improve the control of prescribing and use of antimicrobials in the animal health sector. This includes:

- a) Harmonisation of the technical requirements for the registration of veterinary antimicrobials under one Act. To do this a comprehensive review of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act (Act 36 of 1947) regulating the use of antimicrobials for animal growth promotion and prevention of diseases in animal husbandry will be needed.
- b) A risk assessment should be performed prior to approval of antimicrobials for use in the feed and water of food-producing animals. Such a risk assessment will review all aspects of the approval of the active ingredient, registration of all products containing it, and labels of all such products, and will therefore be the task of a multi-person panel of experts.
- c) Regulated control of the use of antimicrobials in feed mills and via compounding and feeds.
- d) However, risk assessments must be conducted into the impact of proposed changes to prescribing practices in the animal feed sector and that of food security and production before changes are made.
- e) The use of antimicrobials in food production will need to be aligned with international norms and standards, the outcome being the development of a prescribed timeline (2020) for removing antimicrobials used as growth promoters in agriculture that are critical antimicrobials used in human

⁶National Core Standards for Health Establishments, NDoH, 2011 and Regulation 10 of 4 January 2017, Norms And Standards Regulations Applicable To Different Categories Of Health Establishments As Part Of The National Health Act, 2003 (Act No. 61 Of 2003)

health, as per *WHO global principles for containment of antimicrobial resistance in animals intended for food*⁷.

- f) Review of overlapping functions of NDoH: Environmental Health Directorate, municipalities and DAFF for food safety and alignment of legislation regulation on food safety.
- g) Harmonisation of the regulatory requirements around compounding between the Veterinary and Para-Veterinary Professions Act (Act 19 of 1982) and the Medicines and Related Substances Act (Act 101 of 1965).
- h) In animal health, changes to the scope of practice of some para-veterinary professionals is required in order to provide them with training and prescribing privileges for better control of antimicrobial use in animals including them being able to monitor prescribing of and use of antimicrobials and guide farmers, especially small scale farmers in rural areas.
- i) Annual reporting of the use of antimicrobials in animal health will be instituted under the direction of DAFF, using applications under Acts 36 and 101 in addition to data from the South African Revenue Service, which compiles data on imports.

7. Strategic enabler 2: Education and workforce development

These enablers will be focused on building expertise in AMR through education, continuous training and building resource capacity for AMR through workforce development.

Building expertise in AMR

To build expertise, a new emphasis will need to be placed on incorporating the interventions to tackle AMR in the curricula of undergraduate and postgraduate healthcare professionals. These AMR modules are to be included in the medical, nursing, allied health professionals and pharmacy curricula as well as with the veterinary and para-veterinary professionals. This will be done in collaboration with the various health professional councils and training institutions and aligned with relevant OIE Recommendations such as the “Day-One-Competencies of graduating veterinarians” and “Veterinary Education Core Curriculum”.

The development and accreditation of training modules is a medium term goal, however a short-term achievable goal will be supporting continuous in-service training on AMS of health care professionals already in the workplace. This may be effected through the orientation and in-service programs of all Health Establishments, as part of the setting up of AMS committees or structure in Health Establishments or regions, and through AMR continuous professional development (CPD) activities being incorporated into existing CPD requirements for all healthcare professionals.

Workforce development

Workforce development requires a view on sustainability and therefore co-ordination is needed between the various health professional councils, the clinical societies, Deans of medical, nursing, pharmacy and veterinary schools and the NDoH and DAFF.

The correct staffing norm and skill mix of healthcare professional to effectively, efficiently and sustainably able to provide IPC and AMS expertise to all required Health Establishments in the country will be determined. The number of IPC practitioners, microbiologists and Infectious Diseases experts available per Health Establishment or district should be carefully discussed and agreed between the stakeholders with the objective to build up to the required norm over a short period of time.

There is a need for new cadre of animal health technicians who are trained to monitor and control the distribution and use of antimicrobials in rural areas and augment the actions of veterinarians. Improved guidance and education is required to farmers for the purchasing of antimicrobials by the deployment of animal health technicians where OTC antimicrobials are sold. Farmer and veterinarian updates and educational CPD activities need to look at innovative mechanisms to improve access to these programs and impact.

8. Strategy enabler 3: Communication

Targeted campaigns will be developed to increase community awareness on infection prevention and appropriate antibiotic use in both the human and animal health sectors. Active engagement with civil societies will be sought to ensure that communication is tailored in appropriate language and addresses the unique beliefs

⁷ http://whqlibdoc.who.int/hq/2000/WHO_CDS_CSR_APH_2000.4.pdf?ua=1

and practices of communities. Campaigns should also address food preparation and animal health awareness aspects. The risks of AMR linked to inappropriate antimicrobial use should be addressed and the need for appropriate use of antibiotics reinforced. Depending on the targeted population, the most appropriate media of communication will be chosen among the broad range of media available, (e.g. radio, posters, advertisement campaigns, social media), and the use of community health workers to ensure that the right message is delivered to the right community. Existing successful models of community awareness should be emulated and adapted to convey the AMR messages to all. These should form part of the Integrated School Health Program in partnership with the Department of Basic Education.

Use of consumer and patient advocacy groups and community forums to target appropriate messages in the community will be considered.

Gaining the buy-in from the media (television, radio, press) on the global threat posed by AMR will help in fostering a good relationship for future positive coverage of the campaigns initiated such as those for World Antibiotic Awareness Week which will form part of the health calendar awareness activities.

9. Strategy enabler 4: Research

While research and development into new new antibiotics and diagnostic tools is important, delay in new products reaching the market and the workplace highlights the importance of operational and behavioural research to preserve current antibiotics. Mechanisms need to be found to facilitate this research. These include identifying and disseminating funding mechanisms, identifying supervisors, and allocating time and resources.

Priority research areas include:

- Risk assessments in the livestock sector to food security and production relating to changes to antimicrobial prescribing and regulations on use of growth promoters;
- Models of staffing for AMS focused away from infectious diseases specialists to other resource types;
- AMS and IPC interventions to decrease antimicrobial consumption, in humans and animals including behaviour change research;
- Infection prevention challenges specific to Lower Middle Income Countries and how to address them with innovative solutions; and
- Reasons prescribers use antimicrobials inappropriately or how to change people's behaviours to reduce use.

There are a number of research needs related to infection control in South Africa. Examples of some of the operational research needs include:

- Standardised definitions and methodology for collecting surveillance data;
- Effective interventions to sustain hand hygiene compliance;
- Environmental cleaning practices – what is being done currently and what is best practice;
- Risk assessments on biosecurity and hygiene practices in animal health;
- Research into alternatives to antimicrobial therapy;
- Research into more antimicrobial medicines and vaccines that can be used to control clinical disease; and
- Research into the development of disease in humans through exposure of resistant micro-organisms from animals and food products of animal origin.

X. MONITORING AND EVALUATION

The table below describes the short, medium, and long term activities for the monitoring and evaluation (M and E) of the implementation of this National AMR Strategy Framework. As this framework was started in 2014 some of the M and E activities below stem from 2014 period and will continue into the long-term of this strategy.

Activity	2017/2018	2018/2019	2019/2020	2020-2024
Strategic Objective 1: Strengthen, coordinate and institutionalise interdisciplinary efforts (Governance)				
Review and update AMR Strategy Framework to ensure One Health approach and latest evidence	Review	Update/ Publish		Review and Update/ Publish
Functional multidisciplinary, multisectoral One Health Ministerial Advisory Committee on AMR	Quarterly meetings	New membership appointment (2019) Quarterly meetings	Quarterly meetings	New membership appointment (2022) Quarterly meetings
Functional governance structures at provincial levels in health departments	3 provinces	6 provinces	9 provinces	On-going
Functional national coordinating structure for antimicrobial use in food producing animals		Formalise structured established - 3 meetings per annum	3 meetings – per annum	Review structure 3 meetings per annum
Animal health legislation: Review and amend regulations relating to stock remedies	Review and consultation	Update and publish	Implementation of regulations	Implementation of regulations
Animal health legislation: Develop policy on the use of growth promoters (including antimicrobials)		Draft document and consultation	Policy gazetted and implemented	Policy implemented
Strategic Objective 2, 3: Diagnostic stewardship and optimise surveillance and early detection of antimicrobial resistance				
Strengthen surveillance of local and national resistance patterns and antimicrobial use	Surveillance system for AMR in humans established	Surveillance system for monitoring resistance accessible to 3 provincial Department of Health (DoH)	Surveillance system for monitoring resistance accessible to 6 provincial DoH	Surveillance system for monitoring resistance accessible to 9 provincial DoH
		Development of surveillance system for antimicrobial use	Surveillance system for AMR in food producing animals established	Surveillance system integrated for animal, humans and environment

Activity	2017/2018	2018/2019	2019/2020	2020-2024
		in food producing animal		
		Surveillance system for residues in food of animal origin established	Surveillance system for residues in food of animal origin maintained	
			Surveillance for antimicrobials and resistant organisms in environment sources investigated	
Strategic Objective 4: Enhance infection control and prevention				
Prevent infections	Maintain human immunisation program coverage levels			
		Promote immunisation in animals		
Prevent and control the spread of resistant microorganisms in humans and health institutions		Develop a national IPC and HAI plan for surveillance	Implement HAI surveillance and IPC plan	
Biosecurity and hygiene from farm to retail levels		<p>Develop national biosecurity guidelines for different commodity production systems</p> <p>Standardise hygiene guidelines for food producing establishments</p> <p>Develop basic awareness material for good hygiene practice for consumers</p>	<p>Monitor compliance to biosecurity and hygiene guidelines on farm and at food producing establishments respectively</p> <p>Maintain consumer awareness</p>	

Activity	2017/2018	2018/2019	2019/2020	2020-2024
Environmental Health and Water Quality monitoring	Monitor that environmental health policies, Norms and Standards are implemented			
Strategic Objective 4: Promote appropriate use of antimicrobials in humans and animals				
Ensure access to safe, effective and affordable antimicrobials	Create AWaRe* index and monitor annually	Monitor availability of tracer antimicrobials in health facilities		
Institutionalise AMS in human health		Drafting of AMS guidelines for hospitals	Implementation of AMS guidelines for hospitals	Development of AMS guidelines for community practices and primary healthcare
Ensure AMS in animal health		Develop species-specific responsible use guidelines including the use of growth promoters	Update species-specific responsible use guidelines including the use of growth promoters	
		Review legislation on antimicrobial prescribing and harmonisation of drug registration legislation		
		Quarterly awareness sessions to farmers and professionals on judicious usage of antimicrobials		

* AWaRe index is an index created by the WHO to monitor the ratio of use of access, watch and reserve antibiotics in health facilities