NATIONAL STRATEGIC FRAMEWORK FOR PREVENTION AND CONTAINMENT OF ANTIMICROBIAL RESISTANCE

Food, Medicine and Health care Administration and Control Authority of Ethiopia (FMHACA)

Contents

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The discovery of antimicrobials is one of the most important advances in health in human history – alleviating suffering from disease and saving billions of lives over the past 70 years. However their life-saving power is compromised by emergence of antimicrobial resistance and become challenge for treatment of infectious disease like TB, malaria and HIV/AIDS. Promoting proper use of medicines is the only solution we had on hand to combat drug resistance and it's a means through which safe, effective and economic medication is provided to the public. Proper medicines use can be addressed by the collaborative efforts of prescribers, dispensers and the general public. It ensures adherence to treatment and protects citizens from microbial resistance, unnecessary adverse drug reactions, and unnecessary medical cost.

Resistance to antimicrobial medicines is a universal problem, a problem which needs to be tackled by universal action. Microbes are dynamic organisms; therefore our approach to tackling their resistance to antimicrobial medicines must also be dynamic and multifaceted. Therefore this national strategy recognizes the need for a wide range of activities which are required to support the control of antimicrobial resistance and the need for commitment from a wide variety of players including, but not limited to, government agencies, associations, development partners, and universities. It has been developed by a number of stakeholders and endorsed by FMHACA as per the medicines regulatory mandate provided by proclamation number 661/2009 and I hope every concerned party will work effectively to implement this strategic framework. The strategy is supported by plan of action and monitoring and evaluation mechanism which will be printed as separate document.

It gives me a great pleasure to introduce this National Antimicrobial Resistance Prevention and Containment Strategic Framework which signifies the first five years work of what will need to be a sustained long-term program which will be kept under review and developed as necessary.

Finally; I would like to take this opportunity to thank Antimicrobial Resistance Prevention and Containment Advisory Committee and development partners who participated in designing this strategic framework.

Yehulu Denekew Alamneh
Director General, FMHACA

List of Abbreviations and Acronyms

AHRI	Armour Hanson Research Institute
AM	Antimicrobial
AMR	Antimicrobial Resistance
BCC	Behavioral Change Communication
DACA	Drug Administration and control Authority
EDL	Essential Drug List
EHNRI	Ethiopian Health and Nutrition Research Institute
EPHA	Ethiopian Public Health Association
EVA	Ethiopian Veterinary Association
FMHACA	Food, Medicine and Health Care Administration and Control Authority
MOA	Federal Ministry of Agriculture
FMOH	Federal Ministry of Health
HF	Health Facility
HIV	Human Immunodeficiency Virus
IP	Infection Prevention
MLA	Medical Laboratory Association
MOE	Ministry Of Education
MSH	Management Sciences for Health
NACARC	National Advisory Committee on Antimicrobial Resistance and Containment
NAHDIC	National Animal Health Diagnostic and Investigation Center
NGO	Non -Governmental Organizations
PFSA	Pharmaceutical Fund and Supply Agency
RARDB	Regional Agricultural and Rural Development Bureaus
RHB	Regional Health Bureau
RPM Plus	Rational Pharmaceutical Management Plus
SOP	Standard Operating Procedure
SPS	Strengthening Pharmaceutical Systems
STG	Standard Treatment Guideline
TB	Tuberculosis
WHA	World Health Assembly
WHO	World Health Organization

During the past seven decades, antimicrobial (AM) medicines have saved millions of lives, substantially reduced the burden of diseases that were previously widespread and improved the quality of life as well as helped increase life expectancy.

In the recent past, emergence and spread of antimicrobial resistance (AMR) in several microorganisms has rendered the management of many infectious diseases difficult. The development of resistance to drugs commonly used to treat malaria, TB and HIV is of particular concern and an impediment in achieving the related Millennium Development Goals by 2015.

Antimicrobial resistance is a natural biological phenomenon that can be amplified or accelerated by a variety of factors, including human practices. The use of an antimicrobial for any infection, real or feared, in any dose and over any time period, forces microbes to either adapt or die in a phenomenon known as "selective pressure". The microbes which adapt and survive carry genes for resistance, which can be passed on. When antimicrobials are used incorrectly: for too short a time, at too low a dose, or for the wrong disease; the likelihood that bacteria and other microbes will adapt and replicate rather than be killed is greatly enhanced. Much evidence supports the view that the total consumption of AMs is the critical factor in selecting resistance. Paradoxically, under use through lack of access, inadequate dosing, poor adherence, and substandard antimicrobials may play as important a role as overuse. Its Emergence is a result of the use, overuse and misuse both in humans and animals.

The prevention and containment of antimicrobial resistance has a common approach and requires integrated and well coordinated efforts at the national level. It is a biological, behavioral, technical, economic, regulatory and educational problem, and requires a comprehensive response employing evidence based strategy.

As antimicrobial resistance is a global and cross- border issue, the World Health Organization published *The Global Strategy for Containment of Antimicrobial Resistance* in 2001. This key document provides an operational framework and a comprehensive set of containment-related

interventions that reflect AMR's multi factorial nature and which should be implemented by member states by adapting their own framework strategic plan.

In Ethiopia, there are indications on the misuse of AMs by health care providers', unskilled practitioners, animal husbandry and drug users. These coupled with rapid spread of resistant bacteria and inadequate surveillance has exacerbated the problem.

This national strategic framework is designed to make the WHO *Global Strategy for Containment of Antimicrobial Resistance* operational at country level and facilitate our efforts in minimizing the morbidity and mortality due to resistant infections and preserving the effectiveness of antimicrobial medicines.

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The emergence and spread of antimicrobial resistance are complex problems fuelled by the knowledge, expectations and interactions of prescribers, dispensers, and patients, and the regulatory environment. Patient adherence with recommended treatment is another major problem. Easy access of antimicrobials in developing countries and prevalent myths among communities about its use exert an equally important influence on the emergence of resistance.

While resistance can and does appear in any setting, hospitals – featuring the combination of highly susceptible patients, intensive and prolonged AM use, and cross-infection – have become a hot spot for highly resistant bacterial pathogens. Veterinary prescription of AMs also contributes to the problem of resistance. The largest quantities are used as regular supplements for prophylaxis or growth promotion, thus exposing a large number of animals, irrespective of their health status, to frequent sub -therapeutic concentrations of AMs.

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Even if there existed fragmented, specific case oriented, and hospital, research or educational based studies, so far no systematic national studies have been done in Ethiopia to understand the status of resistance, trends or consumption of AM medicines. To fill this gap, the Drug Administration and Control Authority of Ethiopia (DACA) in collaboration with Management Sciences for Health/Strengthening Pharmaceutical Systems (MSH/SPS), has conducted Antimicrobials Use, Resistance and Containment Baseline Survey in 2009.

The results of the baseline survey demonstrated that most bacteria that are involved in causing infections to human beings and animals showed considerable degree of resistance to commonly used first line AM medicines over the five year period (1996-2000 E.C). The baseline survey also indicated a general tendency of increase in resistance over the five years (Refer to the baseline survey document for further information)

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The consequences of resistance, to both individuals and the public, are severe and several. Infections caused by resistant microbes fail to respond to standard treatment, resulting in prolonged illness and greater risk of death. Treatment of infections with resistant strains may require the use of expensive and potentially toxic second or third line of drugs. Treatment failures also lead to longer periods of infectivity, which increase the numbers of infected people moving in the community and thus expose the general population to the risk of contracting a resistant strain of infection. There will be an increase in the cost of treatment, if the condition is treatable at all. Cost associated with longer period of hospitalization and indirect costs due to prolonged absence from work increase the overall cost of resistance. According to the World Health Organization (WHO), AMR is possibly the single biggest threat facing the world in the area of infectious diseases.

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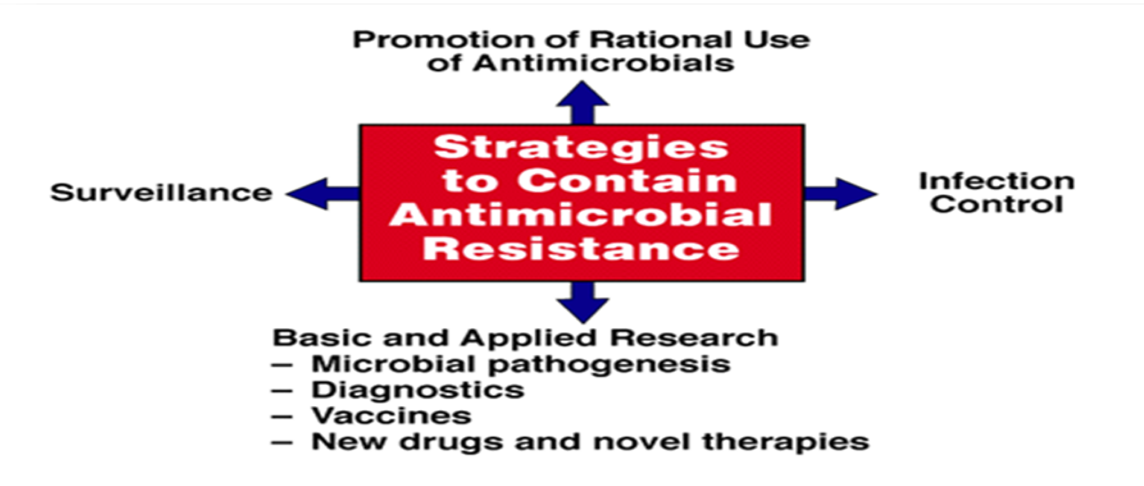
Prevention and containment of AMR requires comprehensive and coordinated response. It was hence essential to develop a national strategy that is simple and practical, is acceptable to

stakeholders, and also acts as a powerful tool to preserve the effectiveness of AM medicines. This national strategy aims to confer particular attention to interventions involving the establishment of laboratory-based networks for the surveillance of resistance, promotion of infection prevention and control activities, and assurance of rational use of AM medicines at all levels of healthcare and veterinary settings.

AMR requires ownership and active participation by several stakeholders, some of which are: the Federal Ministry of Health, the Federal Ministry of Agriculture and Rural Development, the Ministry of Education, the national and regional regulatory authorities, medical, laboratory and veterinary professional bodies, medical and veterinary institutions, national medical and veterinary research institutions, health facilities in public, private and other sectors, international agencies, NGOs, mass media, community and faith based organizations, professional associations, consumer organizations, and other concerned bodies.

This national strategy addresses the following five key strategic issues:

1. Establishing national alliance
2. Surveillance
3. Infection Prevention and Control
4. Rational use of AM medicines
5. Research and Education



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These guiding principles describe the role of all stakeholders to follow a common approach which requires integrated and well coordinated efforts at the national level. They show the impact that this strategy needs to deliver and generally guide on what to do, why to do it, and how to do it. The principals are enumerated as follows:

- Understand the emergence and spread of AMR
- Rationalize the use of available AM medicines
- Prevent emergence of resistance by reducing selection pressure by appropriate control measures
- Bring about a change in behavior of prescribers, dispensers of AM medicines and communities to ensure their rational use
- Combat AMR through nationally coordinated efforts with defined functions by different sectors

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To minimize the morbidity and mortality due to resistant infections and to preserve the effectiveness of AM medicines in the treatment and prevention of microbial infections

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- To establish a national alliance for prevention and containment of AMR
- To institute a surveillance system that captures the emergence of resistance, trends, its spread and utilization of AM medicines in different settings
- To strengthen infection prevention and control measures to reduce disease burden
- To promote rational use of AM medicines at all levels of healthcare and veterinary settings
- To support research and education in the area of AMR prevention and containment

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Strategic Element I: Establishing national alliance

Concerted and nationally coordinated efforts are needed to bring together various stakeholders and harness their expertise and the resources available within the country in different sectors.

Objective: to establish a national alliance for the prevention and containment of AMR
Key elements and major activities that will accomplish this objective are:

Activity 1: Establish a national alliance against AMR

- Establish a team in the Food, Medicine and Healthcare Administration and Control Authority of Ethiopia (**FMHACA**) for coordinating national activities and sharing information with stakeholders and regional governments
- Establish a team (focal points) in regions for coordinating AMR related activities
- Create national alliance of relevant programs and stakeholders from public, private sector, and professional associations
- Form an intersectoral steering committee under the chairpersonship of a high-level policy-maker

- Allocate adequate resources to implement a strategy for the prevention and containment of antimicrobial resistance
- Provide adequate representation of the private sector in the steering committee

Activity 2: Strengthen national networks and collaborate with stakeholders

- Support and coordinate national activities related to AMR
- Strengthen the capacity of regions to implement effective AMR containment and prevention strategies
- Develop linkages with all stakeholders
- Promote regular and formal interactions
- Encourage the role of NGOs in community awareness and targeted education
- Collaborate with the mass media to create awareness
- Collaborate with professional associations to enhance information sharing and incorporate AMR as an important element of continuing education

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Surveillance is essential in guiding clinical management of infections, updating infection control policies, EDLs, and STGs. It is also critical to providing early warning of emerging problems, monitoring changing patterns of resistance, and targeting and evaluating prevention and control measures. Inadequate surveillance means that resistance prevalence and trends are not known and that baseline data for evaluating potential interventions are unavailable. The Antimicrobial use, resistance, and containment baseline survey showed that empiric therapy with AMs is widely practiced. Therefore, establishing and strengthening microbiology laboratories, encouraging antibiotic susceptibility testing, and periodic reporting are important. Analyzing susceptibility and AM use data periodically and sharing to prescribers and other concerned bodies is important. Standardizing methods and procedures for surveillance of AMR and assuring data quality should also be given emphasis. Therefore, an effective network that generate and collate data on resistance and consumption of AM medicines need to be established.

Objective: To institute a surveillance system that captures the emergence of resistance, trends in its spread and utilization of antimicrobial agents in different settings

Key elements and major activities that will accomplish this objective are:

Activity 1: Monitor resistance pattern in microorganisms

- Establish a national and regional surveillance system on AM use, resistance and information dissemination mechanisms
- Support standardization of laboratory methodologies (develop SOP), quality assurance techniques and improve availability and reliability of microbiology laboratory facilities
- Support and conduct culture and sensitivity tests on targeted microorganisms and AMs
- Support and conduct series of population-based, real time surveillance systems to monitor resistance patterns to demonstrate the extent of the problem in both human and animal health
- Ensure the establishment of surveillance network to develop linkages between human and veterinary sectors at national and regional levels
- Quantify resistance patterns of clinically important microorganisms through networks of laboratories equipped with the capacity to perform quality assured AM susceptibility testing
- Disseminate data to users, national and regional focal points and stakeholders
- Encourage healthcare providers to utilize resistance data efficiently

Activity 2: Monitor use of Antimicrobials

- Support series of population-based, real time surveillance systems to monitor AM use to demonstrate the extent of the problem in both human and animal health
- Monitor prescribing patterns in health-care settings in the public and private sectors and the utilization of antimicrobial agents at various levels
- Support the assessment of non-therapeutic use in veterinary and agriculture settings
- Monitor and evaluate the impact of promotion on antimicrobials use
- Disseminate data to users, national and regional focal points and stakeholders

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Infection prevention and control measures in health facilities as well as outside (in community) reduces the risk of transmission of infections and minimizes the need for AMs. This reduces the selective pressure and the subsequent emergence of resistant strains. Furthermore, infection prevention and control measures diminish the spread of the resistant microbes once resistance has emerged. These measures include promoting vaccination, hand hygiene, use of personal protective equipment, maintaining a clean environment, use of antiseptics and disinfectants, decontamination, cleansing and sterilization (or high level disinfection) of instruments, improving safety in risky areas of the health facility, safe use and disposal of sharps, appropriate waste disposal, and isolation of infected patients when required. Partners in many sectors of society and the general public will need to be involved in this effort.

Objective: To promote and strengthen infection prevention and control measures to minimize the emergence and spread of AMR

Key elements and major activities that will accomplish this objective are:

Activity 1: Strengthen infection prevention and control programs

- Expand infection prevention and control systems at national, regional, health facility, and community levels
- Mobilize adequate resources for infection prevention and control (human and material resources)
- Develop, disseminate, monitor, and evaluate infection prevention guidelines, codes of professional practice, accreditation standards (e.g., setting minimum standards) and other relevant resources
- Launch infection prevention and control need based education programs to targeted audience in human and animal health.
- Set minimum accreditation standards for infrastructure of health facilities to promote infection prevention and control
- Strengthen immunization programs in human and animal health

Activity 2: Augment infection prevention and control practices in health facilities

- Establish infection prevention and control practices, and create an enabling environment
- Avail Infection Prevention and control guidelines and monitor their implementation
- Standardize and promote the proper use of antiseptics and disinfectants
- Ensure availability of infection prevention materials
- Establish and strengthen Infection prevention and Control Committee in each health facility
- Conduct regular pre-service and in-service trainings on infection prevention and control
- Develop relevant SOPs for infection prevention and control
- Monitor and evaluate all infection prevention and control practices in the health facilities

Activity 3: Promote infection prevention and control practices in communities

- Develop tools for BCC on infection prevention and control to the community
- Conduct need based health education on infection prevention and control and AMR
- Implement, monitor, and evaluate sustainable health education

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Selective pressure imposed by widespread use (and misuse) of AMs is the primary reason for emergence of AMR. When microbes are exposed to AMs, susceptible organisms are eradicated, whilst resistant once persist, passing on their resistant genes to off-springs by replication or to other species through horizontal gene transfer. There is sufficient evidence that the higher the use of AMs the greater is the resistance to them. Countries, regions, or facilities with higher AM use are associated with higher incidence of resistance. Therefore, judicious use of AMs in both human and veterinary settings is an important strategy to reduce the possibility of emergence of resistance. Overuse and misuse resulting from poor prescribing and dispensing behavior, uninformed patient demand and lack of adherence to treatment regimen prescribed, low-quality

drug formulations, inadequate dosage regimens, and insufficient duration of therapy are also important contributors to AMR. The baseline survey has shown that there is high degree of irrational AM use in Ethiopia. There is also overuse of AMs in veterinary and agriculture settings although the baseline survey didn't evaluate this issue in detail. Animal husbandry is proliferating in our country and hence there is a potential for an increase in irrational use of AMs as this sector expands.

Achieving this strategy involves the strengthening of technical and regulatory requirements along with bringing about a change in the behavior of the prescribers, dispensers and users. Policies and regulations that encourage more appropriate and rational use of AMs are key long-term interventions for the containment of AMR.

Objective: To promote rational use of Antimicrobial medicines in human health, animal health, and animal production.

Key elements and major activities that will accomplish this Objective are:

Activity 1: Promote optimal prescribing and dispensing

- Ensure availability of essential AMs to all health facilities
- Avail and monitor the utilization of drugs lists, STGs, standard prescriptions, guidelines, journals, and other relevant resources to all health facilities in adequate amount
- Develop and disseminate guideline for prophylactic use of AMs
- Design and utilize locally feasible labeling, dispensing, and adherence aids
- Promote sustainable communication among dispensers, prescribers, and providers
- Establish and strengthen DTCs in health facilities
- Provide drug information service and improve and strengthen patient counseling services at health facilities
- Assure information given by pharmaceutical companies is evidence based
- Avail microbiologic diagnostic facilities and ensure their utilization
- Develop antibiotic prescribing and dispensing policies

- ❖ Organize and conduct regular, need-based pre-service and in-service trainings to prescribers, dispensers, and providers

Activity 2: Promote adherence and proper public use

- Design and implement client and public education programs focused on AMs use and resistance prevention and containment
- Empower Consumer organizations to take up AMs and resistance as consumer issues and provide simple, targeted information to consumers
- Empower clients to get information about AMs from health professionals and discourage self medication with AMs

Activity 3: Rationalize antimicrobial use in animal health and production

- Ensure availability of essential AMs
- Work closely with industries involved in animal farm and restrict non-therapeutic use of AMs
- Develop and monitor availability of drugs lists, STGs, guidelines, and relevant resources in animal health and production
- Conduct regular pre-service and in-service trainings on proper use of AMs use, resistance prevention and containment to practitioners in animal health and production
- Prevent over the counter availability of AM medicines
- Conduct regular AM sensitivity test
- Develop feasible labeling, dispensing, and adherence aids
- Empower owner to get information about AMs from veterinary professionals and discourage self-medication with AMs
- Develop AM prescribing and dispensing policy

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Research on AMR issues provides knowledge necessary to develop appropriate response for tackling the emergence and spread of AMR. The type of researches needed in our setting are those that shows the extent and trend in resistance, practices causing resistance and their driving factors, AM use pattern, and strategies that can be applied to prevent and contain resistance. Initiating and encouraging research in these areas should be considered seriously and the capacity of research institutes and academia should be boosted. Work is also needed to translate research findings and recommendations into useful practices. The AMR baseline survey has showed that there are gaps in this area.

Educational works are needed to alleviate the malpractice observed in the use of AMs. In Ethiopia a great deal of educational work, both college/university and continuing education, is being undertaken. However, there are still gaps in addressing the treats AMR has posed and interventions needed to prevent and contain it. Recognition given to AMR by healthcare providers and the public is limited and therefore educating health professionals, patients and the public is a key strategy in addressing AMR issues.

Objective: To promote research and education in the area of antimicrobial resistance

Key elements and major activities that will accomplish this Objective are:

Activity 1: Support basic and operational research

- Support research on issues related to AMR
- Evaluate the impact of use of AMs in agriculture on human health
- Investigate impact of resistance on illness and economy
- Identify factors that influence prescribing habits
- Conduct studies on behavioral aspects about self-medication and adherence, and develop interventions to bring about change

Activity 2: Support education

- Encourage AMR related research activities in universities and colleges; encourage students at both undergraduate and postgraduate levels to take topics linked to AMR and address local context
- Support the revision of course contents of Universities and colleges of medical and veterinary professionals to accommodate topics on AMR prevention and containment.
- Encourage improved continuing education programs to healthcare providers on AMs and AMR
- Train journalists on IP, AMs, and AMR and encouraged them to do programs on these issues
- Incorporate hygiene and IP in teachers' education curricula (health and health related).
- Incorporate hygiene, sanitation, and infection prevention in school curricula

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Resistance to antimicrobial agents is a cross-cutting problem that needs to be tackled by well-coordinated action plan. This national Strategic framework recognizes the need for a wide range of activities which are required to support the control of AMR and the need for commitment from a wide variety of players. It needs to be endorsed by all regions and stakeholders and will lead to sustained action to combat AMR.
The Strategy also recognizes the need for action by many organizations and individuals.

The implementation framework may include followings:

- Obtaining national commitment towards prevention and containment of AMR
- Establishment of a focal point in Food, Medicine and Health care Administration and Control Authority of Ethiopia (FMHACA) responsible to coordinate with the national alliance and empowered to provide evidence-based directives for rational use of AM medicines
- Strengthening of the national expert advisory (steering) committee

- Designation of subgroups in specialized areas within the national committee
- Development of public information campaigns
- Establishment of a national surveillance system with a mandatory reporting system through efficient and quality laboratory networks and existing surveillance systems
- Development of and making available various national standards, guidelines for surveillance and treatment and strengthening regulatory support for their implementation
- Organizing continuing education for professionals and all healthcare workers, and the like, through medical and health-related institutions and professional bodies
- Collation of research findings for developing actions
- Establishment of a national forum of multidisciplinary professionals (health, veterinary, agriculture) to share information to promote the understanding of the impact of use of AM medicines human health
- Collaborate with international agencies for technical support and to obtain recent information
- Conducting regular meetings to review, assess, and modify the action plans

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A strong component of the monitoring and evaluation mechanism through an alliance shall be established.

Data generated must be regularly reviewed to assess performance and the effects of interventions by the national advisory committee and the committee should provide guidance for changes. Performance should be assessed both nationally and regionally. Review meeting shall be organized for this purpose. Implementation action plan that shows details of the activities, responsible stakeholders, time frame, budget etc to guide the implementation of this strategy by the stakeholders will follow and will be printed as a separate document.

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Given the cross-cutting nature of the problem and complexity of the response, it is essential that every stakeholder has clarity about its role in combating AMR, both within its own mandate as well as for those issues which have a bearing upon activities of other sectors. Ownership of the strategy by all stakeholders is critical for it to move forward and yield the desired results. AM medicines failure may occur for many reasons, but it impacts not only patient care and safety but also threatens effective management of infectious diseases. This strategic document is important in showing what needs to be done in this country to prevent the emergence of resistance and contain the spread of resistance.

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