National Antimicrobial Containment Policy

2019 - 2023

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National Antimicrobial Containment Policy 2019 - 2023

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Abbreviations and Acronyms

AMA	:	Antimicrobial Agent
AMR	:	Antimicrobial Resistance
AMSP	:	Antimicrobial Stewardship Programme
AMU	:	Antimicrobial Use
AST	:	Antibiotic Susceptibility Testing
AU-IBAR	:	African Union – Inter African Bureau for Animal Resources
CBO	:	Congressional Budget Office
COMESA	:	Common Market for Eastern and Southern Africa
EAC	:	East African Community
EQAS	:	External Quality Assessment Scheme
FAO	:	Food and Agriculture Organization
GAP	:	Global Action Plan
GDP	:	Gross Domestic Product
GLASS	:	Global Antimicrobial Resistance Surveillance System
HAI	:	Healthcare Acquired Infection
IGAD	:	Intergovernmental Authority on Development
IPC	:	Infection Prevention and Control
LMIC	:	Low and Middle Income Countries
M&E	:	Monitoring and Evaluation
MFDA	:	Maldives Food and Drug Authority
MoFA	:	Ministry of Fisheries and Agriculture
MoH	:	Ministry of Health
MoE	:	Ministry of Education
MoEE	:	Ministry of environment and Energy

NABH	:	National Accreditation Board for Hospitals and Healthcare Providers
NACC	:	National AMR Coordinating Centre
NAP	:	National Action Plan
NHL	:	National Health Laboratory
NRL	:	National Referral Laboratory
OIE	:	World Organisation for Animal Health, Organisation mondiale de la santé animale
OTC	:	Over the Counter
PG	:	Post Graduate
R&D	:	Research and Development
SEAR	:	South East Asia Region
STG	:	Standard Treatment Guideline
UG	:	Under Graduate
WaSH	:	Water, Sanitation and Hygiene
WTO	:	World Trade Organisation
WHA	:	World Health Assembly

Foreword

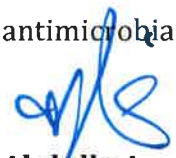
I am honoured to share the first National Antimicrobial Containment Policy in Maldives. Antimicrobial resistance (AMR) is a global threat that requires imperative action. AMR jeopardize the standard treatments, curative measures and facilitates the spread of antimicrobial resistant infections rendering communities in peril.

The policy is in line with the National Action Plan for containment of AMR 2017-2022 endorsed in early 2017, and moving towards the target of curtailing the resistance towards antimicrobials.

This policy sharpens the focus and define the priorities and thrust areas that are evidence based. It will be used as a road map to ensure, continuity of the ability to treat and prevent infectious diseases with effective and safe medicines that are quality-assured, used in a responsible way, and accessible to all who need them.

I wish to acknowledge World Health Organization for the ceaseless financial and technical support. I appreciate the involvement and commitment of Maldives food and Drug Authority and the tireless efforts of Technical Working Groups whose immense inputs and support has made the development of this policy a success.

Ministry of Health remains firmly committed to tackle AMR, as a key component of our top national priority. I believe National Antimicrobial containment policy will strengthen the efforts in reducing the incidence of AMR in Maldives and safeguard the effectiveness of antimicrobials



Abdulla Ameen

Minister of Health

Introduction and Background

Antimicrobial resistance (AMR) affects everybody, regardless of where they live, their health, economic circumstances, lifestyle and behaviour. It impacts sectors beyond human health, such as animal health, agriculture, food security and economic development. The aim to preserve the ability to treat serious infections requires both equitable access to and appropriate use of existing and new antimicrobial medicines. Use of antimicrobials in any form, even when rational and prudent, can precipitate resistance in target microbes.

Growing concerns of antimicrobial resistance

The World Health Organization and its partners have warned of the global rise of resistance against antibiotics, particularly those of "last resort." Therefore, today one of the biggest concerns in the public health domain relates to AMR. Globally, it is estimated that by the year 2050 about 10 million people will die annually from AMR related causes and negative economic effects that may amount to gross domestic product (GDP) losses of >1% and that indirect costs affecting society may be >3 times direct health care costs. Governments across the globe are striving to estimate the crisis in their nation states and the kind of impact it is having on both human and animal life.

Evidence shows that the main drivers of AMR are antibiotic selection pressure and transmission of resistant microbes in both human and animal health sectors[1]. Worldwide, statistics from the industrialized economies show that antimicrobials are extensively used in agriculture and in public health. This trend is likely to be recorded higher in low and middle income countries where rapid growth in populations with incidence of infectious diseases coupled with high demand for animal proteins sourced from intensive farming systems leads to increased antimicrobial use. It is now widely acknowledged that the rate at which AMR is developing and spreading far outstrips the rate at which new antimicrobial drugs are being developed. But drivers at the level of policies and systems also contribute. This complexity calls for a comprehensive, holistic and collaborative approach.

Maldives has made major strides in infectious disease prevention and control such as elimination of Malaria from Maldives in 2015 and successes in TB control. Recently, Government of Maldives has joined other nations in the South East Asia Region (SEAR) speeding up efforts to address the growing AMR crisis.

[1] World Health Organization. Emergence and spread of antimicrobial resistance. Drug resistance. 2016http://www.who.int/drugresistance/AMR_Emergence_Spread/en/

Calling nation states to develop their Global Action Plans on AMR

At the 68th World Health Assembly (WHA) in May 2015, a Global Action Plan on AMR (GAPAMR) was adopted in response to the acknowledgement of this emerging crisis (1). The GAPAMR has therefore been developed at the request of the Health Assembly in keeping with resolution WHA67.25 of May 2014, which was reflective of the global consensus that AMR was indeed a serious threat to human health. GAPAMR was expected to translate into National action plans by May 2017. National action plans should include a strategic action plan, based on a "One Health" approach, bringing together multiple sectors to combat resistance in the local context. The One Health approach provides opportunities to integrate multiple disciplines, working locally, nationally, regionally, and globally to tackle the drivers of AMR emergence with the consideration of the broader Sustainable Development Goals (SDG's).

Maldives has made significant strides in the area of infectious disease prevention and control by focusing major strategic priorities adopted locally, internationally and globally. This is exemplified by elimination of Polio, Malaria, Filaria, Neonationatal Tetanus, Measles and Rubella recently from Maldives and working towards elimination of mother to child transmission of HIV and Syphillis in the Maldives by 2018 and elimination of TB by 2022 in Maldives have begun. Several key steps have been taken by the Government of Maldives that have been instrumental in paving the way for the country to join other nations in the South East Asia Region (SEAR) to speed up its plan on addressing the AMR crisis. Combating AMR would therefore require the highest political commitment in addition to, strong multi-sectoral coordination, sustained investment and technical assistance.

Situation Analysis on AMR for Maldives

A situation analysis was conducted jointly by the government of Maldives and WHO in September 2016 with the objective of assessing the prevalence AMR situation. The analysis helped identify gaps and capacity in the local context. The findings further provided valuable insights which have fed into the development of this National AMR containment policy and NAP AMR.

The situation analysis revealed commitment among the political and technical leadership of the country. They supported AMR containment efforts which were evident through the formation of a National Multi-sectoral AMR Coordination Committee. A fully functional national drug regulatory authority is in place to oversee regulation and licensing, pharmacovigilance and market authorisation of medicines imported and used in Maldives. These efforts clearly stand out as strong elements that have potential to be leveraged as building blocks of an effective AMR containment programme. Similarly, Water, Sanitation and Hygiene (WaSH) related initiatives in human health along with high vaccination coverage have been found to be significant infection control mechanisms within community settings. Finally, limited infection control initiatives in healthcare institutions are seen as opportunities to leverage for instituting effective AMR containment measures in Maldives.

Initiatives are also being taken to develop and draft national standards and guidelines, such as national drug policies, updated essential medicines lists and standard treatment guidelines, including for antibiotic prescription. The Situation Analysis in Maldives revealed that awareness campaigns on AMR have been initiated and on-going. Awareness in livestock and fisheries sector including farmers is yet to be planned and conducted.

Need to generate evidence

However, limited evidence exists with respect to the occurrence of resistant organisms in the nation. Hence, it is difficult to estimate the exact nature and size of antimicrobial resistance (AMR) scenario. Also, it becomes difficult to compare the current situation with other countries in the region. Moreover, limited evidence exists on the trends of use of antimicrobial agents (AMA) in Maldives although, recent prescription audits have indicated overuse of antibiotics, especially for common conditions such as flu, cough and fever. Several gaps in AMR containment system could explain the lack of evidence. An AMR surveillance system that captures standardized epidemiological, clinical and laboratory data on AMR has not been set up in Maldives. A national referral laboratory for AMR surveillance has been identified as the IGMH laboratory which will coordinate with other identified networking laboratories for data collection and data entry. In the absence of systematic data collection and analysis of AMR trends, an early warning system for emerging drug resistance trends is not operational in Maldives yet. Except for limited activities related to education and training

in hand hygiene, standard precautions and additional (transmission related) precautions, there is limited implementation of a systematic Healthcare Associated Infections (HAI) surveillance and Infection Prevention and Control programme.

Medicines including AMAs used in Maldives are imported with no local production; major sources being India, Sri Lanka, Pakistan and Malaysia. However, limited human and technical capacity exists at the National Health Laboratory for testing the quality of imported medicines and food at the points of entry, although a system for post-marketing surveillance system is in place under MFDA for both imported medicines and food. Antibiotic potency testing has been initiated in NHL to assure the quality of antibiotics in the Maldives market.

Generating evidence related to AMR will help:

- *Estimate the exact nature and size of AMR scenario in the country*
- *Provide greater clarity on usage trends of AMA*
- *Establish a national laboratory AMR surveillance system*
- *Ensure systematic data collection and analysis of AMR trends*
- *Set up early warning system for emerging drug resistance trends*
- *Push for a more systematic implementation of Healthcare Associated Infections (HAI) surveillance and Infection Prevention and Control programmes*
  Strengthen human and technical capacity at the National Health Laboratory for testing quality of imported medicines and food

A focused strategy to monitor and improve antimicrobial agents

The Antimicrobial Stewardship program (AMSP) as an important strategy for monitoring and improving the use of AMAs in different health care settings is yet to be introduced in Maldives's health sector. Accordingly, surveillance for AMU is not operationalized in Maldives even though data collection has been initiated from 2016.Maldives's health system is characterized by a substantial presence of expatriate doctors. This has added to lack of standardization of treatment guidelines and wide variation in prescription practices, including use of antimicrobials.

Inspite of modest institutional capacity, public health research in general and AMR research specifically has not caught the attention of the research community.

Traditionally, lack of animal populations and commercial orientation of food animal production systems based on terrestrial animals has led to limited development and capacity of veterinary health services. Accordingly, majority of the food consumed in Maldives is imported into the country. Recently, the Government of Maldives has laid emphasis on

diversification into poultry and goat farming as well as aquaculture with the objective of attaining greater food security. This calls for greater attention to the problem of AMR and antimicrobial use (AMU) in veterinary sector. As of now, the animal health sector, in general, lags behind in AMR containment efforts.

Why a National AMR Containment Policy for Maldives?

Health policy refers to decisions, plans, and actions that are undertaken to achieve specific health care goals within a society. A National policy is being proposed as a commitment of Government of Maldives to the global and national efforts for containment of AMR, while reinforcing the government's commitment to make universal healthcare and animal welfare, food safety, nutrition and security a reality. The Policy outlines five interrelated objectives for action by the Maldives Government in collaboration with partners in healthcare, public health, veterinary medicine, agriculture, food safety, and academic, and industrial research. The proposed National AMR containment policy aims to achieve the following:

- Define a vision for AMR containment in Maldives in future;
- Help establish AMR containment targets and points of reference for the short and medium term;
- Outline priorities and thrust areas that are evidence based, effective, acceptable and fair;
- Outline the expected roles of different groups; and
- Build consensus (integrate different initiatives and sectors outlined in the NAP AMR) and informs stakeholders.

National AMR Containment Policy: Goal, Principles and Objectives

The National AMR Containment Policy identifies priorities and coordinates investments to prevent, detect, and control outbreaks of resistant pathogens recognized as urgent or serious threats, which are naturally resistant to many drugs used to treat other infections and proliferate following administration of antimicrobials. It ensures continued availability of effective therapies for the treatment of microbial infections; and to detect and control newly resistant microbes that emerge in humans and/or animals.

Implementation of specific policy interventions provided under each objective will help to reduce the incidence of AMR in Maldives. National targets for reducing serious and urgent threats by 2020 are provided in Table 3.

Goal

The overall goal of this policy is to provide an overarching framework to ensure, continuity of the ability to treat and prevent infectious diseases with effective and safe medicines that are quality-assured, used in a responsible way, and accessible to all who need them.

The National AMR policy will be guided by the following principles enshrined in the Global Action Plan for AMR:

Principles

Whole-of-society engagement including One Health approach: Engaging with all sectors and disciplines and focusing on preservation of effectiveness of antimicrobial medicines through well designed conservation and stewardship programmes.

Prevention first: Emphasising on the prevention aspect which is critical since it minimizes need for treatment. In the context of low and middle-income countries (LMIC) this is highly recommended since it is cost effective and can be implemented in resource constrained settings. Good sanitation, hygiene and other infection prevention measures will slow down development and restrict spread of difficult-to-treat antimicrobial resistant infections.

Access: A comprehensive AMR containment policy to ensure equitable access to and appropriate use of, existing and new antimicrobial medicines. Effective implementation of such a policy will depend largely on access, inter alia, to health facilities, health care professionals, veterinarians, preventive technologies, diagnostic tools including "point of care" tests, knowledge, education and information.

Sustainability: Call for political commitment and international collaborations that promote technical and financial investment. The AMR containment policy will assess resource needs and provision for long-term investments in surveillance, operational research, laboratories, human and animal health systems, competent regulatory capacities and professional education, training in human and animal health sectors.

Incremental targets for implementation: AMR containment efforts require a multipronged strategic approach, this policy is geared towards certain thrust areas, that are backed by evidence for their success in different settings, especially in LMICs. The policy thus provides for flexibility into determining the priority actions that are needed to take in order to attain objectives and to implement the actions in a stepwise manner that meets both local needs and global priorities.

Objectives

The national AMR policy is guided by five objectives which form the basis for developing an effective public health response to AMR in Maldives.

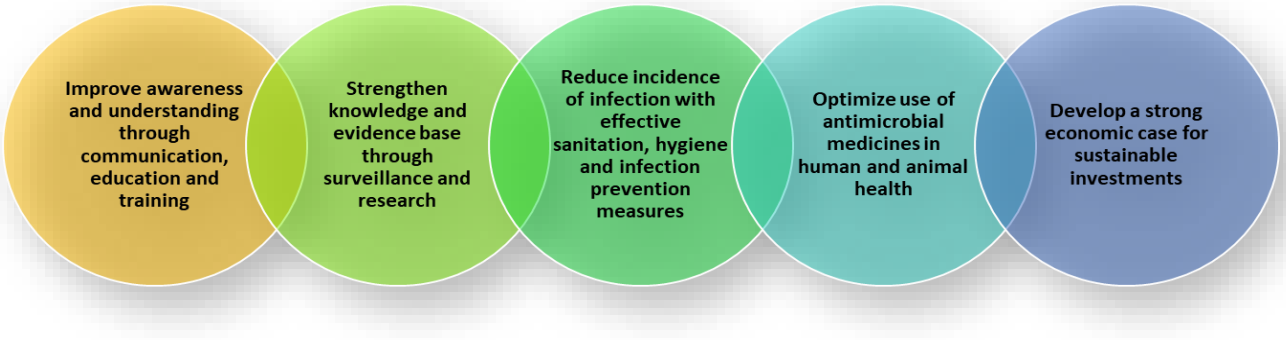


Figure 1: Objectives of National AMR Containment Policy of Maldives

1. **Improve awareness and understanding through communication, education and training:** Effective behaviour change communication will help target different audiences in human and animal health and agricultural practice as well as consumers. Starting early by revising school curricula will instil AMR related messages in formative years. Including AMR as a core component of professional education, training, certification and continuing education will be critical for those in the health, veterinary sectors and agricultural practice.
2. **Strengthen knowledge and evidence base through surveillance and research:** Surveillance and basic, translational, clinical, social, economic and behavioural research will address priority knowledge gaps on incidence, prevalence, range across pathogens, geographical mechanisms of emergence, spread and patterns related to AMR. They will inform local, national and regional actions and feed into monitoring mechanisms.
3. **Reduce incidence of infection with effective sanitation, hygiene and infection prevention measures:**
   To limit development and spread of antimicrobial resistant infections and multidrug-resistant bacteria in humans/animals, infection prevention must be a priority. Use of existing and newer vaccines and sustainable animal husbandry practices must be an ongoing effort.
4. **Optimize use of antimicrobial medicines in human and animal health:** Regulatory frameworks should support distribution, quality and use of medicines while also encouraging investment in R&D. Promoting evidence-based prescription and dispensing of antibiotics through effective, rapid, low-cost diagnostic tools will guide

optimal use of antibiotics in human and animal medicine and establish a surveillance system to monitor their use.

5. **Develop a strong economic case for sustainable investments:**
   Evaluate national needs and conduct economic impact assessment on health and the broader socioeconomic burden of AMR. Compare cost of doing nothing against the cost and benefit of planned action.

Policy priorities: Evidence-based and context-specific for greater impact

The absence of progress in combating antimicrobial resistance is partly due to an insufficient or poor evidence base for the effectiveness of the myriad policies across the human health and animal sectors. Even in countries where policies have shown benefits in reduction of antimicrobial use or resistance, robust and complete policy assessments have been insufficient, with little information on cost-effectiveness and inadequate descriptions of the technical, political, and regulatory environment necessary for implementation.

Evidence however suggests structural and regulatory reform policies or behavioural interventions are more context specific than policies targeting other areas of antimicrobial resistance control (e.g., hospital stewardship or resistance monitoring). In this context it is the latter that are more effective and this is particularly true for LMICs.

In LMICs, the policies with greatest potential to reduce the need for antimicrobials are infection prevention and control (including vaccinations, hand washing, improved access to water and sanitation). Stewardship programmes in both outpatient and hospital settings, more so in secondary care settings and improved resistance surveillance and antimicrobial use monitoring data, also contribute to ensuring accountability. Improved monitoring of drug quality to curb the production of counterfeit and substandard antimicrobials is another vital aspect when it comes to minimizing undue dependence and use of antimicrobials.

The AMR Policy for Maldives is based on rigorous situation analysis. Policy thrust spans across all five objectives namely, awareness and knowledge about AMR, infection prevention and control, rational use and antimicrobial stewardship; surveillance of AMR, AMU and research and innovation. The evidence based interventions that are being proposed have been found to be globally effective and generalizable in LMIC settings. The fact that they are locally acceptable, implementable, fair and sustainable makes for smoother implementation.

Priority 1: IPC to reduce spread of infections in human and animal care food systems and community

Infection prevention and control, especially in the context of hospitals, is an important aspect of a strategic plan to contain AMR since clinical settings represent an ecosystem of high antimicrobial usage. In the absence of local standard guidelines, awareness, training and resources, the quality and scale of implementation of IPC in health care settings has been less than optimal. Other measures such as an AMR stewardship programme in healthcare settings or ambulatory settings, in human and animal health, food sectors and HAI surveillance are yet to be established. A National AMR stewardship program for humans, have been drafted and is ready for finalization and implementation.

On the other hand, better hygiene (WaSH) and Infection prevention control represent methods to cut down on the spread of infections in ambulatory human and animal care facilities, in food systems and in the community in general. Vaccination in humans and animals and biosecurity in food systems are specific interventions that if implemented effectively, can result in better health outcomes and reduced risk of emergence of AMR.

Maldives has made major strides in providing improved WaSH facilities in health facilities, as is exemplified by 82% and 100% population having access to improved sanitation and drinking water. Similarly, 99.4% DTP3 coverage demonstrates the deep penetration of existing infection prevention initiatives through vaccination. However, limited production of food of animal origin, particularly terrestrial animals, has not led to much policy focus being given to vaccination and biosecurity.

Maldives AMR policy will help initiate an AMR stewardship programme in health care/ambulatory settings, in human and animal health and food sectors and HAI surveillance. It will also make way for specific interventions related to vaccinations in humans and animals, pushing for greater biosecurity in food systems.

Recent focus on plans to achieve greater food security for Maldives, especially in the field of aquaculture and poultry highlights the need to have preventive strategies in place in order to address the problem of AMU and AMR before it starts. As a priority under the National AMR Containment Policy, Maldives will:

- Establish a national infection prevention and control programme through full implementation and compliance with the IPC guidelines within healthcare settings, animal health care, and food systems and environment

- Implement a healthcare facility-based HAI surveillance system along with related AMR surveillance to monitor the incidence, burden, mechanisms of spread and control of AMR in healthcare settings;
- Promote sanitation and hygiene through social mobilization and behavioural change activities to limit development and spread of AMR outside health settings;
- Augment a vaccination programme in the human sector and introduce standardized animal vaccination schedules that are enforced as per international guidelines, to address the upcoming policy emphasis enhancing food security through indigenous production of food of animal origin; and
- Implement vaccination with IPC/biosecurity measures introduced in animal including food production sectors.

Priority 2: Promote rational use of antimicrobials, antimicrobial stewardship and surveillance of use/sales

Use of antimicrobials in any form, even when rational and prudent, can precipitate resistance in target microbes. High antibiotic use is reflected in over-prescription and easy access through over-the-counter sales, which are widespread in many countries. Maldives has a fully functional National Regulatory Authority, namely the Maldives Food and Drug Authority, that is responsible for regulation and licensing; drug import and pharmacovigilance. Post licensing inspections including for retail pharmacies and OTC sales are carried out on national scale regularly. However, limited human and technical resources as well as the complex challenges of import based system of procurement limit the effectiveness of regulatory activities.

The AMSP as an important strategy for monitoring and improving the use of AMAs in different health care settings has been introduced in Maldives's health sector. Development of National STG has been initiated. Currently, the treatment guidelines, including for use of AMAs, are guided by empirical evidence and adapted by local physicians and surgeons in hospitals. Local STGs are seldom guided by local AMR surveillance data. Substantial presence of expatriate doctors is believed to be significant contributor to this lack of standardization.

The Maldives AMR policy will place emphasis on strengthening human and technical resources as well as address some of the complex challenges of import-based systems of procurement that have so far limited the effectiveness of regulatory activities.

Surveillance for AMU is not yet operationalized in Maldives. However, efforts have been made to analyse antimicrobial import data which could tally as the national consumption data. Similarly, surveillance for use in hospital and ambulatory care settings has not been initiated. A recent survey of over-the-counter (OTC) sales of prescription-only medicines including AMAs conducted by MFDA in 2015 revealed 25% pharmacies violating the regulatory provisions reference: pharmacy inspection assessment report 2015, 2016 and 2017). They also point towards the presence of irrational use in spite of a rigorous monitoring system. Moreover, the animal health sector lags on all of the above fronts and is further constrained by lack of regulatory powers.

Maldives will establish a robust system for regulation and surveillance of use of antimicrobial agents for control of use of antimicrobial substances in human, animal and food production sectors. Some of the measures taken will include an empowered National Drug Regulatory Authority; import frameworks favourable to regulatory requirements; National AMR Containment Policy and related regulatory frameworks; standard treatment

guidelines with special reference to use of antimicrobial agents;National Antimicrobial Stewardship Programme and AMU monitoring programme in human , food and animal production systems, ambulatory and community settings and including; and residues testing in food products and waste water.

The National AMR Containment Policy recommends a robust system for regulation and surveillance of use of antimicrobial agents. This will help control use of antimicrobial substances in human, animal and food production sectors, serving as a strategic priority through the introduction of following:

- Regulation of existing antimicrobials
    - Introduce a separate schedule for antimicrobial agents for greater regulation of use.
    - Introduce special labelling of (e.g. colour coding) all antibiotics and all new molecules like Carbapenems (Ertapenem, Imipenem, Meropenem), Tigecycline, Daptomycin, thus restricting their access to only tertiary hospitals.
    - Curtail the availability of fixed dose combination of antibiotics in the market, except for naturally interactive ones.
- Extend the regulatory framework of MFDA to include control of antimicrobials to be registered under full dossier submission which includes antimicrobials used in companion animal practices, fisheries/aquaculture, poultry.
- Strengthen regulatory compliance through favourable import procurement systems and make it possible to get bulk procurement system of drugs including AMAs.
- Introduce drug price control with special reference to antimicrobials.
- Consider enforcing Codex standards (or a local adaptation) as mandatory compliance measure for imported foods.
- Incorporate regulatory powers with Ministry of Fisheries and Agriculture to control use of antimicrobials in aquaculture, poultry and goat farming; restricting growth promotion use of antimicrobials in poultry, goat farming.
- Include pets under in the definition of animals; regulate sale and use of antimicrobials for treatment of pets.
- Establish surveillance of quality of imported drugs to enforce quality standards of antimicrobial drugs (veterinary, human, and food production sectors)
- Enact the Animal Health Act that empowers the Ministry of Fisheries and Agriculture to strengthen biosecurity through regulation of importation of animal species (including birds, poultry, small ruminants, aquatic, pet animals), use of antimicrobials in aquaculture, poultry and goat farming; vaccination of terrestrial and aquatic animals; and good agricultural practices.
- Develop and implement public health standards with special reference to antimicrobial stewardship and infection prevention and control in health care facilities; extend a voluntary system of accreditation on priority to tertiary care, regional and Atoll hospitals.

- Ensure that the Environment Protection Act provides for special consideration for antimicrobials in medical and farm waste pre-treatment standards; also to help protect and/or mitigate the emergence of resistance in environment, especially in units that are likely to use antibiotics.
- Establish a national Antimicrobial Stewardship Programme to improve/measure use of antimicrobials.
- Develop essential medicine lists and standard treatment guidelines with special reference to AMAs and for antimicrobial use in human and animal health care and food industry.

- Establish mechanisms to monitor antimicrobial usage to inform interventions to reduce overuse and promote prudent use of antimicrobial substances by:
    - Monitoring import and sales data for antimicrobials use in humans as well as animals.
    - Monitoring the quantity and quality of AMU data in different settings through point prevalence surveys for humans and animal sector, including, in the hospitals and ambulatory settings

Priority 3: Surveillance of AMR

The GAP AMR identifies the need to establish an evidence-based surveillance for AMR in the nation. To achieve this, a broad cross-sectoral, multi-stakeholder programme of harmonization and integration of AMR surveillance systems should be fostered to enable in-country and between-country comparisons of antibiotic use and resistance. WHO GLASS surveillance standards[2] have been recommended to enable an ordered integration of country and regions into a globalized AMR surveillance system.

In Maldives several elements of systematic AMR surveillance such as surveillance standards/guidelines, laboratory standards, systematic data collection and analysis including electronic reporting, recording and linkage with HAI surveillance are not in place in different sectors. Human health sector has an institutional level bacterial AST. However, animal health sector has no AMR surveillance in the emerging food animal production systems of poultry, goat farms and aquaculture.

The National AMR Policy recommends that Maldives will consolidate its strengths in AMR surveillance and develop a high quality AMR surveillance system that will integrate AMR surveillance in laboratories, hospitals, AMU and surveillance in animal sectors through:

- Development of a multi-centric surveillance system to provide early warning of emerging resistance and monitoring of secular trends at national and sub-national levels. With One Health as a principle enshrined, National AMR surveillance programme will span humans, animal and food industry as well as environmental sector and involve public and private sectors.
- Building lab capacity under leadership of a National Referral Laboratory (NRL) to produce high-quality microbiological data for patient and food-safety management and support surveillance activities.
- Establishment of a national early warning system on AMR hazards with central database on AMR risk information by establishing a systematic, standardized process to collect, assess and share data, maps and trends on AMR hazards; develop communication and

The Maldives AMR policy will establish an evidence-based surveillance for AMR using the WHO GLASS surveillance standards[1] to enable an ordered integration of country and regions into a globalized AMR surveillance system.

[2]WHO has developed the Global Antimicrobial Resistance Surveillance System (GLASS) to foster standardized AMR surveillance. globally.
http://apps.who.int/iris/bitstream/10665/188783/1/9789241549400_eng.pdf)

dissemination systems to ensure coordination and information exchange; and initiate responses to warning triggers.

- Setting up of a central library or database to store AMR risk information that can make data available to government agencies, public and international community

- Establishing AMR surveillance data automation and centralization through electronic systems of AMR surveillance data entry, storage and transmission in human clinical, food testing labs to guide policy making and programme planning at the national level.

Priority 4: Raise awareness amongst general public and professionals on AMR

Awareness campaigns on AMR have been initiated mainly targeting the general public including schools, but also reaching out to the executive council of Minister of Health, clinicians in public and private hospitals, nurses, pharmacists, allied health professionals and government officials in health and other sectors. Awareness in livestock and fisheries sector including farmers is yet to be planned and conducted.

The GAP AMR focuses:

- On making AMR a core component of the professional education training, certification, continuing education, development in the health, veterinary sectors, agricultural practice.
- On promoting behavioral changes through public communication programs that target different audiences in human health, animal health and agricultural practices as well as a wide range of consumers related to these sectors.
- On promoting interventions eminently supported by social mobilization.

Maldives will continue to carry out nationwide awareness campaigns and curricular reforms as an important policy intervention under the National AMR Containment Policy.

The Policy recommends:

-Conducting nation-wide evidence-based awareness campaigns with regular M&E with messages targeting priority groups that include school students and teachers, general public, policy makers, clinicians, pharmacists, nursing staff, farmers in poultry/goat/ aquaculture farming.

-Incorporating AMR and related themes (such as hand washing and hygiene) in school curricula, and revisions curriculum especially in professional development course and undergraduate/ postgraduate curricula

The Maldives AMR policy will build on existing awareness and advocacy efforts through nation-wide, evidence-based awareness campaigns with multiple target groups, incorporating AMR and related themes. The policy includes monitoring and evaluation components to assess awareness levels, impact of advocacy and streamline future efforts to reinforce key messages.

Priority 5: Research and innovation:

The GAP AMR posits that the economic case should reflect the need for capacity building and training in low resource settings, while developing evidence based interventions to reduce infections and combat AMR. The 2001 strategy for AMR containment could not achieve its goals; one of the reasons cited for the same is that there was absence of economic assessments, which evaluated the cost of doing nothing versus the cost/benefits of action at the present.

The Maldives AMR policy will strengthen capacity building and training while developing evidence based interventions to reduce infections and combat AMR. It will guide policy and programme relevant research through systematic mapping of institutional capacities and encouraging AMR related research and innovation, amongst others.

Research on AMR is new to Maldives for both policy maker and research community. However, academia, the Maldives National University has initiated an AMR research through the University grants. The existing limitation in evidence on the nature and extent of AMR as a public health.

The lack of evidence-based information on the AMR calls for policy and programme to be formulated through based on research support planning.

1. Maldives have identified research priorities in health sector, where assessment of AMR situation and assessment of antibiotic prescription and consumption patterns in Maldives are requisite. This is crucial for the development of the functional and sustainable health system in the country.

Maldives has limited capacities in terms of technical expertise, infrastructure, finance needed for the research. Hence it is crucial to the national AMR policy recommends the conduct of systematic mapping of institutional capacity and gaps for AMR research and innovation.

Maldives will provide a policy framework, funds for program and relevant research through:

- identification of cost effectiveness and feasibility of interventions to reduce AMR and AMU across different sectors. These will then feed into midline and end line review of the national Antimicrobial Containment policy.
- Establishing of several research and innovation networks and platforms with the objective of mutual learning and benefits of resource pooling and the setting up of a multi-stakeholder platform and research consortia that will generate programme and

policy relevant evidence. This will be a key strategy for Maldives, given its existing nature of AMR threat and limited institutional capacity.

- Identification, pooling of funds and utilization these funds from various institutional in support for research and innovation.

Partnerships and Implementation framework

A national multi-sectoral steering committee, co-chaired by the delegated Ministers of Health and Fisheries & Agriculture, will be established under which a technical coordination committee. (National AMR coordination committee) will be functioning to implement the activities of a National Action Plan for Combating AMR that will detail the specific steps that different agencies are taking, or will take, both individually and in coordination to implement this National Antimicrobial Containment Policy. Under the National AMR coordination committee, 5 technical subcommittees as per the 5 strategic objectives will be actively performing their roles and responsibilities to facilitate the implementation of National Action Plan for containment of AMR. Specialized task force groups can be assigned by the subcommittees for conducting different tasks.

The National Action Plan will establish clear milestones and metrics for success. These activities will be coordinated by a technical coordination committee (National AMR coordination committee). Because this initiative will require a sustained effort, the coordination committee will report to the national steering committee on progress made in implementing the National Policy and Action Plan, and toward achieving national targets.

It is expected that departments and agencies indicated below would take steps to combat antibiotic resistance that are not explicitly included in either the National Policy or Action Plan. Complementing their efforts would be industry and other non-governmental organizations as well as international partners who will play a key role in accelerating progress in combating antimicrobial resistance.

This National Policy will solidify an ongoing partnership among these entities to ensure resources are leveraged effectively to address the urgent threat of AMR in the ultimate interest of public health and national security.

Proposed Institutional Framework

The implementation of this Policy will be undertaken by:

Public Sector:

- Ministry of Health
    - MoH will provide leadership in the Implementation of this Policy and host the multi-sectoral Secretariat for the AMR agenda. The MoH will provide leadership in the implementation of the AMR agenda within the Health Sector.
- Ministry of Fisheries and Agriculture
    - The MoFA will provide leadership in the implementation of the AMR agenda in the Livestock, Fisheries and Crop sub sectors. The MoFA will be part of the AMR secretariat.

- Ministry of Environment and Energy
    - MoEE will support implementation of the AMR agenda with respect to the Environment
- Ministry of Education
    - MoE will provide leadership in human resource capacity building for effective implementation of the Policy. In addition, research and evidence to inform policy will be generated through the institutional network of Ministry of Education
- Other Government Ministries, Departments and Agencies (MDAs)
    - While carrying out their mandates, relevant Ministries, Departments and Agencies will support specified roles in the AMR agenda.
    - Local Government (City council , Local Government Authority, Atoll Council , Island Council)The Departments responsible for Health will provide leadership in the implementation of this Policy at the city, atoll and Island in addition to implementation of the AMR agenda within the Health Sector.
    - The Department responsible for Veterinary Services will provide leadership in the implementation of the AMR agenda in the Livestock and Fisheries
    - The Department responsible for Environment will support implementation of the AMR agenda with respect to the Environment.
    - Other Departments and Agencies while carrying out their mandates will support specified roles in the AMR agenda.

Role of private sector

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

Role of international agencies

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

Legal frameworks

Existing legislation will guide the implementation of this Maldives National AMR Containment Policy. Wherever necessary these will be reviewed and new ones developed to incorporate the AMR agenda. Relevant legislations/regulations and their salient features applicable for implementation of national AMR containment policies are enlisted below:

Regulation/Act	**Provisions applicable to National AMR Containment Policy**
Health Services Act	Article 65, clause 1
Revised Medicines Regulation Act	Article 2
Animal Health Act (draft)	AMR Regulated issues to be incorporated
Fisheries Law	AMR Regulated issues to be incorporated
Aquaculture Policy (draft)	AMR Regulated issues to be incorporated
Health Care Facility Quality Regulation	
Codex Alimentarius	All standards
Medicine Regulation	Article 6, clause, 7.9, 7.19 , 9.1,9.2
AMR control Regulation(draft)	

AMR coordination mechanism

The implementation of Maldives National AMR policy will be done within the framework of a National AMR Action Plan designed on the lines of GAP AMR. The governance mechanism will comprise of national multi-sectoral committee, National AMR coordination committee, Technical subcommittees and specialised Task Forces related to the five strategic objectives of GAP.

The national multi-sectoral committee will provide the necessary political commitment and platforms for programme planning and implementation for national AMR containment efforts in Maldives. Technical subcommittees will provide technical inputs such as, conducting situational analyses, drafting NAPs, planning and budgeting, commissioning specialised task forces and overseeing implementation of strategic interventions and corresponding key activities under the five strategic objectives. Specialised task force groups will be commissioned for delivering on specific tasks in the respective strategic areas. The task force groups will be tasked with functions such as evaluation of existing policies, frameworks, interventions and guidelines and the development of guidelines and standards.

Financing

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

Monitoring, Evaluation and Review

This Policy is a progressive document that will be reviewed as and when necessary using standardized assessment frameworks. In view of the complexity of designing assessments, a multi-sectoral task force would be convened through the National AMR Coordinating Committee (NACC)for this purpose. Standardized analyses of contextual factors (e.g. political structures, governance and regulation, and resource availability) would be included. Detailed case studies and policy examples will be developed to enable assessment, review and comparisons of best practices.

Policy will be monitored annually. It is proposed that a mid-term policy review will be undertaken in 2020 followed by an end-line review in 2023. Maldives' National AMR Containment Policy will set the following targets:

National targets for combating AMR

The indicative, quantitative targets are outlined below. These targets are aligned to achieve AMR containment goals while reinforcing the government's commitment to make universal healthcare and animal welfare, food security a reality in keeping with the policy thrust. Looking ahead, building on the goals set in 2017, by the year 2022 the Republic of Maldives would have achieved:

- 15% reduction in HAI and associated AMR in health care facilities
- 10% (in patient) and 25% (outpatient) reduction in antimicrobial use in human
- 25% reduction in antimicrobial use in animal
- 50% increase of public and professional knowledge on AMR and awareness of appropriate use of antimicrobials
- Improved capacity of the national AMR management system in all seven focus areas of AMR containment efforts[3]

[3]WHO SEARO developed a regional roadmap to guide Member States in developing their national AMR prevention and containment programmes and implement the NAP. The roadmap proposed five phases of development, which are based on the activities and actions implemented as a part of the NAP. In phase 3 (phase of initial implementation), the country initiates and implements an AMR prevention and control programme at the national level. During this phase, a functional model of the AMR programme is developed, but in limited scale.

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