Strategic and Operational Guidance
for
National Action Plan on Antimicrobial Resistance for Developing Countries
Focusing on animal and environment aspects

Based on:
International Workshop on National Action Plan on Antimicrobial Resistance for Developing Countries

Organised by

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CONTENTS

FOREWORD

Antimicrobial resistance (AMR) has been globally recognised as an emerging threat to public health which is linked with high disease and economic burden on people and nations. It is also linked with food, nutrition, livelihood and Sustainable Development Goals. AMR is a 'One Health' issue, which recognises that health of humans, animals and ecosystems are interconnected. It needs to be addressed through cross-sectoral coordination among multiple stakeholders.

In recent years, the momentum to combat AMR has increased. Ever since the adoption of 'Global Action Plan on Antimicrobial Resistance' in 2015, the WHO-FAO-OIE tripartite is supporting development of National Action Plans to be submitted by mid-2017. The issue of AMR has also got global political support at the United Nations General Assembly during September, 2016.

Historically, certain developed countries, particularly of the European Union have been addressing AMR through systematic policy and practice initiatives. The scenario is different in developing world due to limited awareness and resources as well as weak laws and implementation. In global context and more so in case of developing world, human side of the problem has received most attention and environment part of the issue has got least.

Centre for Science and Environment (CSE) has been working to highlight and address the animal and environmental aspect of AMR in India. Recognising the challenges of the developing world, CSE organised a two-day international workshop to develop guidance for National Action Plan (NAP) on AMR for developing countries. Experts from the tripartite and several developed and developing countries successfully came up with strategic and operational guidance on animal and environment aspects of NAP during the workshop held at New Delhi in November, 2016.

It came out that the food animal production is potentially a significant contributor to emergence and spread of AMR. The environmental spread of AMR deserves much greater attention both in global guidance and country-level action plans. There are best practices and learnings from developed countries, which developing countries should consider adopting based on their country-level scenario. The expert group collectively developed guidance on three key areas i.e. responsible antibiotic use, surveillance of antibiotic use and antibiotic resistance, and environment management. Timelines are also proposed alongside. The guidance reflects what should be a part of a NAP to contain AMR spread through animals and environment.

We hope that this report helps the developing countries in formulating both strategic and operational part of their NAPs on AMR. We expect that concerned stakeholders consider adopting the guidance based on respective country-level scenario. We also hope that representatives of the tripartite at the national, regional and global level are benefited and the outcome of this report is incorporated in subsequent global guidance and country-level campaigns to address one of the biggest threats to public health in recent times.

1, INTRODUCTION

Antimicrobial resistance arises when microorganisms survive exposure to a drug that would normally kill them or stop their growth. Antibiotic resistance (ABR) specifically is resistance to antibiotics that occurs in bacteria. With antibiotics becoming increasingly ineffective against disease-causing bacteria, AMR is being recognised as an emerging public-health threat. It can lead to greater spread of infectious diseases, difficulty in treating common infections, uncertainty in success of high-end procedures, longer hospital stays and more expensive treatments. The misuse and overuse of antibiotics in both humans and animals accelerates ABR. In intensive food-animal production settings, as in poultry, pig and fish farms, antibiotics are routinely used for reasons other than treating sickness, i.e. for non-therapeutic purposes such as growth promotion and mass disease prevention. Rampant use is known to lead to greater transfer of antibiotic residues and resistant bacteria into humans through food, direct contact and the environment. Additionally, AMR is expected to impact economies, leading to reduction in global Gross Domestic Products, increased poverty, decline in global livestock production as well as exports[1]. By 2050, AMR has been estimated to lead to 10 million deaths per year and lost outputs worth US $100 trillion across the world[2].

Historically, there has been concerted action to address the animal and environment aspect of the AMR in certain developed countries such as Denmark, Sweden and Netherlands. Limited action has been observed in developing countries in this regard, which present a different set of challenges. These include inadequate policy framework, limited stakeholder awareness, ineffective implementation of laws, limited focus on infection prevention and control, dearth of technology and resources and huge information gaps. The problem is expected to aggravate in view of growing demand for protein from animal foods and intensification of food animal farming practices.

Across the world, there has been an increase in the momentum to address the threat from rising AMR. In 2015, the World Health Organization (WHO) adopted the 'Global Action Plan on Antimicrobial Resistance'[3]. The Plan (also known as GAP) laid out several measures as per five strategic objectives and underscores the need to limit emergence and spread of AMR through antibiotic use in humans, animals, and the agriculture sector. The GAP emphasizes the need for an effective 'One Health' approach through cross-sectoral coordination among multiple stakeholders. Recognising the variability in national resources, the GAP calls for member states to develop and submit NAP by mid–2017. The WHO is engaged in a tripartite with the Food and Agriculture Organization of the United Nations (FAO) and the World Organization for Animal Health (OIE) to support implementation of the GAP[4]. A high-level meeting on AMR was also held at United Nations General Assembly (UNGA) in September, 2016 to garner strong political commitments. This was the fourth time in the history that a health issue had been addressed at the UNGA. Additionally, the 'Action Plan on Antimicrobial Resistance 2016–2020'[5], and 'Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials'[6], were also released by the FAO and OIE respectively this year, aimed at supporting the implementation of the GAP and development of NAPs.

[1]Drug Resistant Infections: A Threat to Our Economic Future
http://www.worldbank.org/en/news/infographic/2016/09/18/drug-resistant-infections-a-threat-to-our-economic-future
[2]Tackling Drug-Resistant Infections Globally: Final Report And Recommendations
http://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf
[3]Global Action Plan on Antimicrobial Resistance, WHO
http://www.wpro.who.int/entity/drug_resistance/resources/global_action_plan_eng.pdf
[4] The FAO-OIE-WHO Collaboration A Tripartite Concept Note
http://www.who.int/influenza/resources/documents/tripartite_concept_note_hanoi_042011_en.pdf?ua=1
[5]The FAO Action Plan on Antimicrobial Resistance 2016-2020 http://www.fao.org/3/a-i5996e.pdf
[6]The OIE Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials
http://www.oie.int/fileadmin/home/eng/media_center/docs/pdf/portailamr/en_oie-amrstrategy.pdf

AMR has been recognised as a 'One Health' issue encompassing humans, animals, agriculture and the environment. The tripartite has reflected on the importance of containing AMR spread through a holistic and multi-sectoral approach[7]. However, the environmental aspect deserves much greater attention.

The international workshop, organized by the CSE aimed at developing guidance for NAPs for developing countries with reference to limiting resistance from antibiotic use in food animals as well as environmental spread of AMR. The workshop brought together about fifty global, regional and national experts from governments, inter-governmental organisations, civil society as well as the scientific community from both human and veterinary sector. Experts from countries who have championed the cause of AMR such as Denmark, Netherlands, Sweden, the UK as well as from developing countries such as Bangladesh, India, Kenya, Philippines, South Africa, Sri Lanka, Thailand and Vietnam participated in the workshop. There was representation from the WHO and OIE (from the regional level) and the FAO (from headquarter and regional level).

Considering the relevance for developing countries, the workshop involved deliberations on three key areas i.e., responsible antibiotic use, surveillance of antibiotic use and antibiotic resistance and environment management. The workshop facilitated exchange of views on best practices, challenges, learnings, and ground realities. The expert group collectively developed guidance for National Action Plan for developing countries at the strategic and operational level.

[7]FAO-OIE-WHO Factsheet http://www.oie.int/fileadmin/Home/eng/Media_Center/docs/pdf/FAO_OIE_WHO_AMRfactsheet.pdf

2. SUMMARY OF DELIBERATIONS[8]

AMR is a quintessential 'One Health' issue encompassing humans, animals, agriculture and the environment. A multi-sectoral approach is critical to combat AMR at a national-level and so is collaboration at the regional and international level. It is important that all stakeholders adequately recognise the problem and aggressively work towards the solution. These include policy makers, regulators, human and animal health practitioners, farmers, drug industry, scientific community, civil society and consumers. AMR, particularly the animal and environment aspect of it, does not get due focus in the developing part of the world. Some developed countries of the European Union have made systematic efforts towards containing AMR over the last two-three decades. There are best practices and learnings, which developing countries may consider adopting based on their country-level scenario.

2.1 ANTIBIOTIC USE IN FOOD ANIMALS

Antibiotics are worldwide used in food animal production such as in terrestrial and aquatic livestock for both therapeutic and non-therapeutic purpose. While therapeutic use pertains to treatment of the sick, non-therapeutic use involves routine administration of antibiotics in a group of animals to prevent disease (mass disease prevention) and to enhance feed efficiency or weight gain (growth promotion) through feed and water. Such non-therapeutic use is most often an alternative to good animal husbandry and biosecurity measures and is aimed to cushion the ill-effect of high stocking densities in intensive animal farms. Even antibiotics which are critically important for human beings and considered as a last-resort such as colistin are used in routine.

Antibiotic use in animals is known to have strong linkages with emergence and spread of antibiotic resistance. A large proportion of antibiotics produced are used in food animal production. The global livestock consumption of antimicrobials is estimated to increase by 67 percent by 2030. Two thirds of this increased use is expected due to growth in number of food animals and remaining is due to increased intensification of farms and high demand of animal proteins. Collectively, in Brazil, Russia, India, China and South Africa, this consumption is estimated to increase by 99 percent[9]. Livestock in developing countries has a significant role in rural livelihoods and country-level economy and nutrition.

In developing countries, indiscriminate use of antibiotics is also linked with no or weak regulations, inadequate implementation and limited stakeholder awareness. For example, over-the-counter (OTC) availability of antibiotics, online marketing of antibiotic-laden feed and feed premixes, limited control on quality of antibiotics including those imported. Farmers have low technical know-how and they are unaware of implications of antibiotic misuse and overuse. They are often misguided by representatives/distributors of antibiotic-laden products. There is limited support through veterinary advisory, diagnostic capacity. Programmes targeted at veterinarians and farmers to promote judicious use of antibiotics are not common. Certain regulatory initiatives were considered inadequate to address the AMR problem such as the Animal Feed Act in Sri Lanka and the advisory to limit growth promoter use in poultry in India. Few recent initiatives include the AMR pledge for veterinarians in Philippines, restriction on colistin use by South African Veterinary Council and the Veterinary Law in Vietnam.

[8]The summary observations reflect a general sense of the house on developed and developing countries based on specific country-level inputs shared

[9]Van Boeckel *et al*. (2015) Global trends in antimicrobial use in food animalshttp://www.pnas.org/content/112/18/5649.full.pdf

The European Union (EU) has prohibited use of antibiotic growth promoters since 2006. In case of certain developed countries of the EU, well before 2006, there has been continued focus on ensuring health of animals and concern for public health implications of antibiotic use in food animal production. Country-level initiatives have been evidence backed, supported by relevant research and analysis of antimicrobial use and resistance trends. For example, in Denmark, antibiotics can be procured only through prescription and administered to animals only under veterinary supervision. Veterinarians do not earn any incentives by selling medicines. Antibiotics are sold only from licensed pharmacies. Voluntary phase-out of 3rd and 4th generation cephalosporins is now being considered.

Similarly in Netherlands, prophylactic use of antibiotics has been banned since 2011. All antibiotic use is prescription only and administered exclusively by a veterinarian. Fluoroquinolones, 3rd and 4th generation cephalosporins are allowed after mandatory susceptibility testing. Antibiotic reduction targets are set at national level. At farm-level, quantitative benchmark indicators through color codes are used to control antibiotic use. Each farm is required to register all antibiotic use in a centralised database to ensure transparency. In case of Sweden, antibiotics are used exclusively for treating the individual sick animal and not administered in groups for non-therapeutic use. The sale of antibiotics is also restricted and the law does not allow veterinarians to earn money by selling antibiotics. Sweden has guidelines for optimum use of antibiotics in food animals, and has restricted the use of quinolones and new generation cephalosporins.

Besides, regulatory approaches, there has been considerable and concerted effort in awareness creation and changing attitude of farmers and veterinarians on judicious use of antibiotics. Significant attention has been put on biosecurity and use of alternatives. For example, the 'Swedish model 'emphasizes on animal welfare, rearing of healthy animals, good farm management and controlling or eradicating infectious diseases through appropriate sanitation, biosecurity, and food hygiene. Alternate actions to treatment with antibiotics and selective dry cow therapy are presented to the farmers. Similarly, in Netherlands, the use of antibiotics has been replaced by improved biosecurity, vaccination and herd health management.

Globally, necessary interventions are required across the value chain to contain AMR from animals. These include strengthening veterinary capacity, extending reach of veterinary advisory through allied professional services and shifting animal husbandry practices to sustainable and cleaner models. Other critical interventions include adequate financial and technical support, innovation in development of alternatives such as vaccines; complementary technologies such as point-of-care diagnostics; and stewardship practices. Similarly, importance of engaging consumers in demanding antibiotic free products; and promoting appropriate labelling of food from animals needs to be underlined. For example, investor and consumer pressure have led major restaurant companies in the US to limit antibiotics in their meat supply.

Promotion of sustainable diets through dietary guidelines and consumer awareness may also help reduce antibiotic consumption in food animals. Rising incomes are linked with more meat production and consumption. Intensification is also linked with industry consolidation and export potential. There is need for reassessment of trade and investment treaties in this sector.

2.2 SURVEILLANCE OF ANTIBIOTIC USE AND ANTIBIOTIC RESISTANCE

Surveillance of antibiotic use (ABU) and AMR (antibiotic resistance in particular) across human and food animal sectors is critical to the success of AMR action plan. Analysis of integrated surveillance data is a key to understand the existing scenario and aid formulation of future policy and guidance on practice to contain AMR.

In developing world, a huge information gap is data on consumption of antibiotics in animals. It is likely the case with information on human antibiotic use in most cases. There are hardly any national-level surveillance programmes on tracking the quantum and trends of antibiotic use in livestock and fishery sector. Collecting such data is challenging. There are no initiatives to collect and collate antibiotic user, prescription, sales and production data. There is limited information in most cases. For example, import data on select antibiotics is available in countries such as in Sri Lanka and Kenya. In South Africa, only few veterinary pharmaceutical companies are said to have agreed to divulge data related to antibiotic usage. There is no such data from pharmaceutical industry in India.

Another area of critical concern is surveillance of AMR in food animals, leading to inadequate data and understanding. Reasons include absence of concrete surveillance framework, inadequate infrastructure, dearth of qualified resources and limited availability and sustainability of funds. For example, The South African National Veterinary Surveillance and Monitoring Programme for Resistance to Antimicrobial Drugs (SANVAD) was initiated in 2000, but was discontinued after the completion of the grant in 2007. Most developing countries do not have any systematic national level surveillance programmes. Sporadic, patchy and sentinel studies are however carried out by specific research groups or institutions to decipher drug resistance trends. Moreover, these studies cater largely to the surveillance of AMR in humans and not animals. There is hardly any integrated surveillance information generated which encompass AMR data from humans, food animals, meat or environment. For example, in India, AMR surveillance is focused on humans so far.

The situation is different in certain developing countries leading the fight against AMR cause through systematic surveillance programmes. For example, the Danish Integrated Antimicrobial Resistance Monitoring and Research Programme (DANMAP), Monitoring of Antimicrobial Resistance and Antibiotic Usage in Animals in the Netherlands (MARAN), and Swedish Veterinary Antibiotic Resistance Monitoring (SVARM). In addition, recognising the importance of resistant genes in the emergence of AMR, Denmark is currently exploring possibilities of whole genome/community for detection of resistance genes. In all these cases, surveillance results are transparent and published periodically for greater dissemination. Importantly, monitoring of antibiotic sale and consumption is linked to these programmes. This has led to reduction and control over antibiotic use over the years. For example, in Netherlands, a decline is reported in total sale of antibiotics, use of colistin, fluoroquinolones and 3rd and 4th generation cephalosporins. Denmark through appropriate legal structures conducts herd-level monitoring of antibiotic consumption. VetSTAT (Danish system for surveillance of the veterinary use of drugs for production animals) collects consumption data at target species and herd level. Veterinary practitioners, wholesalers and licensed pharmacists are required to report directly to the VetSTAT with necessary data. Additionally, the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project under the European Medicines Agency collects data based on reporting from wholesalers or holders of marketing authorizations. The data is useful for comparison between member states.

Food chain is an important route for spread of resistant bacteria or genes. In addition, antibiotic residues in food are linked with selection for resistance in humans. Besides resistance, monitoring antibiotic residues in food from animal origin is significant. A comprehensive antibiotic residue monitoring

framework and programme is lacking in developing countries. Residue standards do not cover all food categories and antibiotic use. For example, in India, there are no Maximum Residue Limits (MRLs) for chicken meat, eggs or milk. On the other hand, countries like South Africa have adopted standards set by CODEX Alimentarious.

2.3 ENVIRONMENT MANAGEMENT

AMR has been recognised as a 'One Health' issue. AMR linkages to the environment are crucial to address but as of now get least priority. The issue is complex and research gaps exist but there is sufficient case to focus on this aspect. Many developed countries have been addressing environmental dimension of AMR spread. Despite greater need, environment has not really been a priority in developing countries. Environmental laws and their compliance is a concern in these countries. The linkages exist with farms and factories. This includes waste from food animal farms, slaughter houses, meat and dairy processing units, pharmaceutical research and manufacturing units, healthcare and veterinary care settings as well as disposal of unused antibiotics.

Farm waste is potentially a significant source of AMR spread. Misuse and overuse of antibiotics in food animal production leads to transfer of antibiotic residues and resistant bacteria and genes into terrestrial and aquatic environment through farm generated waste. In view of high prevalence of infectious diseases, limited biosecurity, insufficient hygiene and sanitation and increased use of antibiotics, AMR spread from farms into the environment is of critical concern in the developing world. For example, in parts of India, aquaculture farm waste is found to be released directly into canals, sewage drains or agricultural fields without treatment. Poultry litter is often used as manure in agriculture fields. The situation is likely to be similar in other developing countries. Further, aquatic environment around certain pharmaceutical hubs in India and China containing high concentration of antibiotic APIs (Active Pharmaceutical Ingredients) is considered a huge concern due to sheer size of the export-oriented antibiotic industry in these parts of the world.

While there is a need for more research on environmental aspects of AMR, emerging evidence related to the transmission pathways of resistance determinants among livestock, people and environment as well as impact of contributing factors is gradually being consolidated. Research has shown that farm waste added to soil can considerably change the antibiotic resistance gene abundance. Among developing countries, Thailand and Bangladesh have studied the environment spread of AMR in animal farm samples, poultry litter, pig manure, stagnant and drainage water from pig farms, waste water, surface water, supply water, fresh vegetable produce and wild and domestic birds.

While the tripartite has reflected on the importance of containing environmental spread of AMR, the issue deserves much greater attention and articulation in terms of how countries are to move ahead specifically in view of growing evidence of environmental spread. Also, the nature and gravity of the problem calls for an active involvement of a global environmental organisation.

A review of the AMR NAPs of different countries with reference to the efforts to address environmental spread of AMR, suggest that most countries underscore the importance of inspection, prevention and control, and bio-security but specific measures to tackle waste from pharmaceutical or food animal production settings is not common. The environmental dimension gets greater mention in NAPs of developed countries, wherein the need for intensifying research or initiating environmental monitoring is highlighted. For example, Canada, US and UK refer to the need for research-based data to understand the mechanism and routes of environmental dissemination of AMR. On the other hand, the NAPs of Switzerland, Netherlands, Japan, Australia and Norway consider environmental monitoring. In particular, Switzerland underscores the need for monitoring antibiotics in farmyard manure, soil and water. Netherlands stresses on monitoring manure and waste water from health facilities, treatment plants and residential areas. Japan emphasizes on researching surveillance of resistant bacteria as well as residues in aquatic and terrestrial environment. Sweden talks about controlling pharmaceutical waste[10].

3. STRATEGIC AND OPERATIONAL GUIDANCE

In order to develop the guidance, the expert group under each overarching area i.e., responsible antibiotic use, surveillance of antibiotic use and antibiotic resistance and environment management, identified a set of themes and collectively finalised interventions and proposed timeframe alongside. The reference timeframe is as follows:

- Short-term **(S)** for an intervention that should be completed within one year
- Medium-term **(M)** for an intervention that should be completed between 1-3 years
- Long term **(L)** for an intervention that should be completed between 3-5 years.
- In case the intervention needs to continue throughout, the timeframe is presented as **(S-M-L)**

The guidance is intended to support strategic and operational parts of animal and environment aspects of NAPs on AMR for developing countries. The countries are expected to consider this and incorporate in their respective NAPs based on country-level scenario. Additionally, representatives of the WHO-FAO-OIE tripartite at the national, regional and global level may consider the output of this report and include in their subsequent global guidance and country-level campaigns.

[10]National Action Plans on Antimicrobial Resistance: Need for Greater Focus on Environmental Spread: http://www.cseindia.org/userfiles/factsheet-national-actionplan.pdf

3.1: STRATEGIC AND OPERATIONAL GUIDANCE FOR RESPONSIBLE ANTIBIOTIC USE

		THEMATIC AREAS				
		Supply of antibiotics	**Production Systems**			**Consumers**
			Reduce need for antibiotics	**Veterinarians and veterinary services**	**Farms and Farmers**	

INTERVENTION AREAS	**Policy/ Law/ Regulations/ Standards/ Programmes**	• Assessment of existing laws and regulatory framework before formulation of new laws **(S)**
		• National policy and regulatory framework on responsible antibiotic use with focus on **(S)**:
		  ○ Approval and authorisation of antibiotics for animals
		  ○ Standard treatment guidelines for treating animals
		  ○ Ban/phase off of non-therapeutic use such as for mass disease prevention and growth promotion
		  ○ Restricting use of critically important antibiotics for humans
		  ○ Antibiotic use under supervision and prescription
		  ○ Mitigating livelihood impact on small holder farmers
		• Regulation to restrict antibiotics in animal feed and premix, registration of feed and premix, prescription and use of only registered products **(S)**
		• Regulation on import of feed, feed premix and antibiotics for animal use **(S)**
		• Labelling law for feed, premix **(S)**
		• Labelling law for antibiotics for specie-specific use **(S)**
		• Regulation on online marketing and direct distribution of antibiotics, premix, antibiotic feed or any other
			• Develop guidelines for biosecurity **(S)**
			  ○ Plan/programme for internal and external biosecurity and its enforcement
			  ○ Programme to support small-holder farmers to implement biosecurity
			• Programme to research, develop, promote access to alternatives such as vaccination, probiotics etc. **(S)**
			• Plan for research and development of appropriate animal breeds **(S)**
				• Law for licensing / registration of veterinarians **(S)**
				• Law to delink antibiotic prescription and incentives **(S)**
				• Programme for accessible, affordable and quality diagnostic services to support judicious use of antibiotics **(S)**
				• Programme for targeted, livestock specific veterinary services to provide free advisory services to farmers **(M)**
					• Law for licensing and monitoring of commercial farms and farmers (such as intensive/semi-intensive farms or all farms based on country-level scenario) **(M)**
					• Programme to incentivize/dis-incentivize farmers based on extent of antibiotic use **(S)**
						• Labelling law for food from animals produced with or without antibiotics **(S)**

		THEMATIC AREAS				
		Supply of antibiotics	**Production Systems**			**Consumers**
			Reduce need for antibiotics	**Veterinarians and veterinary services**	**Farms and Farmers**	
		products with antibiotics **(S)** • Law to ensure licensing of manufacturer, distributor and sellers of antibiotics, feed, premix and other inputs **(S)** • Law to ensure prescription sale, including penalty for unauthorized sale **(S)** • Plan to set reduction targets for antibiotic use by a certain date and with a review process **(S)**				
	Implementation tools- Infrastructure/ Capacity/ Systems/ Resources	• Authority for approving veterinary drugs and market authorization **(S)** • Systems to enable data collection of antibiotic production, sale and import **(M)** • Necessary enforcement systems through agencies, customs, infrastructure, human resource including those required for auditing/inspecting companies providing inputs (e.g. feed), ensuring prescription sale etc.**(M)**	• Develop systems to ensure adoption and implementation of appropriate biosecurity measures at the farm level **(M)** • Systems to register antibiotic free alternative products and their use **(S)** • Support to programmes on development and adoption of vaccines **(M)** • Investment and research in development of appropriate animal breeds **(M)**	• Set up licensing authority for veterinarians and those involved in fisheries **(S)** • Develop capacity and infrastructure to ensure veterinary diagnostic services **(M)** • Develop system to dis-incentivize antibiotic prescription by veterinarian **(S)**	• Set up licensing authority for farms and registration of farmers **(S)** • Enabling system to dis-incentivize/incentivize antibiotic use at farm level **(M)**	• Systems to ensure compliance of labelling laws **(S)**
	Advocacy / Awareness and Education/ Training/ Curriculum	• Awareness and training of regulators, customs officials, distributers and sellers to ensure approved sale, documentation etc. **(S-M-L)**	• Awareness and training of farmers, registered practitioners, veterinarians and other stakeholders on need for biosecurity, judicious antibiotic use and importance of alternatives **(S-M-L)**	• Awareness, training and education of veterinarians **(S-M-L)** • Necessary AMR focus in curriculum and continuous professional medical education **(S-M-L)**	• Targeted education on AMR and judicious antibiotic use for farmers **(S-M-L)** • Farmer training in agro-ecological/alternative farming practices, participatory farming approaches **(S-M-L)**	• Consumer awareness on antibiotics in food and AMR, labelling of food from animals raised without antibiotics and role of sustainable diets **(S-M-L)**

	THEMATIC AREAS				
	Supply of antibiotics	**Production Systems**			**Consumers**
		Reduce need for antibiotics	**Veterinarians and veterinary services**	**Farms and Farmers**	
					• Awareness and promotion of Institutional procurement of food not raised with antibiotics (such as through a score card system used to incentivize/dis-incentivize food procurement) **(S-M-L)**
Record keeping/ Database generation/ Collation/ Dissemination and Research/ Survey	• A national database of licensed antibiotic producer, importer, seller including defaulters available online **(S)** • An online national/regional/sub-regional database on antibiotic production, sale and national database on import **(M)** • Online dissemination of updated policy, regulation and data including list of approved and unapproved antibiotics **(S)** • Annual report of antibiotic sale correlated with consumption and resistance data **(M)**	• A national database available online for approved and unapproved vaccines and other alternatives **(S)** • A list/database/rating of farmers/producers successfully adopting biosecurity and using alternatives and not antibiotics **(M)**	• A national database available online of registered veterinarians, and those who prescribe more antibiotics and without testing **(M)** • An updated list of diagnostic services available **(S)**	• A national database available registered farms and farmers including those who are non-compliant or use more antibiotics **(M)**	• Publically available database of farmers/producers raising food from animals without use of antibiotics **(M)** • Database of farmers/producers not in compliance to labelling laws **(M)**
Review / Monitoring / Feedback	• Periodic review and mapping of antibiotic production, import, sale as per sectors with consumption and resistance data for continued advocacy, awareness and future policy and practice **(S-M-L)** • Annual report on antibiotic sale **(S-M-L)**	• Periodic review of use and success of alternatives, with reference to antibiotic use and resistance data at the farm / sub-regional / regional / national level **(S-M-L)**	• Periodic monitoring of records at veterinary levels **(S-M-L)**	• Periodic monitoring of records at farm levels **(S-M-L)**	Periodic assessment of initiatives with those of antibiotic use data **(S-M-L)**

3.2: STRATEGIC AND OPERATIONAL GUIDANCE FOR SURVEILLANCE OF ANTIBIOTIC USE AND ANTIBIOTIC RESISTANCE[11]

		THEMATIC AREAS			
		Antibiotic use	**Antibiotic resistance**	**Antibiotic residues**	**Environmental surveillance**
INTERVENTION AREAS	**Policy/ Law/ Regulations/ Standards/ Programmes**	• Assessment of existing laws before formulation of new laws **(S)** • Legal provision for obtaining farm-level antibiotic use data **(S)** • Regulation to ensure prescription audit of veterinarians/authorized practitioners **(M)**	• National AMR surveillance programme to monitor resistance in animals and food from animals across all sectors **(S)** • Law compelling farmers and food processors to provide samples for analysis and share their internal data on resistance **(S)** • Establish ambitious and achievable resistance reduction targets **(S)**	• National antibiotic residue monitoring policy/programme in food from animals **(S)** • Standards for antibiotic residues in food from animals such as chicken, eggs, milk, fish (**S)**	• National AMR surveillance programme to monitor resistance in environment **(S)** • Regulation on antibiotic residues in effluent and waste from industries and farms **(S)** • Standards for waste discharge from farms, slaughter houses, animal food processing industry, pharmaceutical industry and healthcare settings **(S)**
	Implementation tools- Infrastructure /Capacity/ Systems/ Resources	• Systems to enable collection and collation of farm-level antibiotic use data **(M)**: o Harmonized system for data collection and analysis o Ensure farmer's responsibility to provide data o Factor-in priority markets/sectors	• Commission an expert advisory group/steering committee to decide on key elements such as networking experts/labs, develop, terms of reference, priorities, linkages and international collaboration **(S)** • Identify, establish and strengthen national reference laboratories who decide upon standards, protocols, organisms, data management mechanisms **(M)[12]:** o Ensure quality and harmonization with national/international data and establish linkages with resistance in humans and environment o Enable collaboration across labs to	• Develop comprehensive residue monitoring framework which enables surveillance of approved and unapproved antibiotic use **(S)[13]** o Export oriented residue monitoring framework could be considered for adaptation based on domestic antibiotic use • Ensure availability of required funds, infrastructure and resources for quantitative data collection **(S)**	• Monitoring and surveillance framework including monitoring of antibiotic residues and AMR in indicator bacteria in environment, farms, factories, slaughter house, wet market, processing unit, health care facilities, vet care facility (prioritization based on ground realities) **(M)** • Assess infrastructure needs, accordingly build/strengthen appropriate infrastructure

[11]Surveillance is recommended across a One Health framework, across each theme including human, food animal, food product and the environment
[12]Refer 'Integrated Surveillance of Antimicrobial Resistance', guidance from a WHO Advisory Group, AGISAR. The document should also consider including guidance on environmental surveillance
[13]Maximum Residue Limits (MRLs) and Risk Management Recommendations (RMRs) for residue of veterinary drugs in foods issued by CODEX could be referred

		THEMATIC AREAS			
		Antibiotic use	**Antibiotic resistance**	**Antibiotic residues**	**Environmental surveillance**
			provide support, build access to WHO, FAO and OIE labs • Develop and strengthen lab infrastructure, professional capacity, standardization of sample collection and testing protocols and assure quality both internally and externally through External Quality Assurance Scheme. **(M) -**sector specific; **(L) -** integrated quality assurance • Ensure surveillance systems for harmonization across all sectors such as animal, human and environment. Integrated surveillance could begin with a pilot initiative **(S-M-L)**		and capacity **(M)** • Develop systems to adapt, standardize, compare data across countries **(M)**
	Advocacy / Awareness and Education/ Training/ Curriculum	• Awareness campaigns for farmers to self-police themselves and keep records **(S-M-L)** • Awareness campaigns for veterinarians/authorised practitioners to prescribe antibiotics judiciously and keep records **(S-M-L)** • Training programme on documentation for farmers and veterinarians/authorized practitioners **(S)** • Training needs assessment of those conducting surveillance, development of training material and protocols for data collection and management followed by enabling environment to collect data **(S)** • Advocacy at community and	• Awareness campaigns on importance and need of resistance surveillance across stakeholders **(S-M-L)** • Training needs assessment for those conducting surveillance **(S)** • Development of training material and protocols for resistance data collection and management followed by enabling environment for resistance surveillance **(S)** • Capacity building and training programmes including integrated programs with the WHO,FAO,OIE collaborating centers **(M)** • Advocacy at community and institutional level based on antibiotic resistance data reports **(S-M-L)**	• Awareness campaigns on importance and need of residue monitoring **(S-M-L)** • Training needs assessment for those conducting surveillance **(S)** • Development of training material and protocols for residue testing and data management followed by enabling environment **(S)** • Capacity building and training programmes **(M)** • Advocacy at community and institutional level based on antibiotic residue data reports **(S-M-L)**	• Awareness campaigns on importance and need of environmental surveillance across stakeholders **(S-M-L)** • Training needs assessment for those conducting surveillance **(S)** • Development of training material, protocols and data management **(S)** • Capacity building and training programme (including at university level) **(M)** • Training of peer/participatory monitoring systems **(M)** • Advocacy at community and institutional level based on environmental surveillance data reports **(S-M-L)**

	THEMATIC AREAS			
	Antibiotic use	**Antibiotic resistance**	**Antibiotic residues**	**Environmental surveillance**
	institutional level based on antibiotic use data reports **(S-M-L)**			
Record keeping/ Database generation/ Collation/ Dissemination and Research/ Survey	• Online systems for collating and analyzing prescription data and farmer use data. This should include antibiotics and classes, weight as unit, total antibiotic consumption in different food sector, therapeutic and non-therapeutic use **(M)**[14] • Surveys at farm level for data collection across different sectors **(M)** • Setting up of data standards, ensuring the quality assurance of data **(S)** • Establishment of national repository, publishing of annual reports and public dissemination of data to ensure transparency **(M)**	• Data collection, collation and analysis at regional and sub-regional level from laboratories, food processors, imported food and those generated from surveys at farm-level **(S-M-L)** • Correlation with antibiotic use and residue data **(S-M-L)** • Development of an online integrated information system and publishing of annual reports and public dissemination of data to ensure transparency **(M)** • Develop early warning system **(S)**	• Data collection, collation and analysis at regional and sub-regional level from laboratories, food processors, imported food and those generated from surveys at farm-level **(S-M-L)** • Correlation with antibiotic use and resistance data **(S-M-L)** • Development of an online integrated information system and publishing of annual reports and public dissemination of data to ensure transparency **(M)**	• Data collection, collation and analysis at regional and sub-regional level **(S-M-L)** ○ Selection of sentinel sites to begin with • Correlation with animal antibiotic use and AMR data **(S-M-L)** • Development of an online integrated information system and publishing of annual reports and public dissemination of data to ensure transparency **(M)** • Develop early warning system **(S)**
Review / Monitoring / Feedback[15]	• Periodic review and mapping of data on antibiotic use, resistance and residue as part of integrated surveillance for continued advocacy, awareness and future policy and practice **(S-M-L)**	• Periodic review and mapping of data on antibiotic use, resistance and residue as part of integrated surveillance for continued advocacy, awareness and future policy and practice **(S-M-L)**	• Periodic review and mapping of data on antibiotic use, resistance and residue as part of integrated surveillance for continued advocacy, awareness and future policy and practice **(S-M-L)**	• Periodic review and mapping of data with antibiotic use and resistance in animal and human for continued advocacy, awareness and future policy and practice **(S-M-L)**

[14]Information available at OIE could be referred

[15]Review as per integrated surveillance mechanism; Member countries to decide frequency and mechanism of review or monitoring

3.3: STRATEGIC AND OPERATIONAL GUIDANCE FOR ENVIRONMENT MANAGEMENT[16,17]

		THEMATIC AREAS			
		Registration/Licensing (based on environment risk assessment)	**Biosecurity/Sanitation & Hygiene/Good Manufacturing Practices**	**Waste Management**	**Research**
INTERVENTION AREAS	**Policy/ Law/ Regulations/ Standards/ Programmes**	• Policy on registration of farms, factories, slaughter houses, wet markets, processing units, feed manufacturers, health care facilities, veterinary care facilities **(S)** • Siting guidelines and licensing for farms, factories, slaughter houses, wet markets, processing units, feed manufacturers, health care facilities, veterinary care facilities **(S)** • Policy on environment risk assessment for registration and renewal of antibiotics for humans and animals **(M)**	• Development of guidelines, best practices for farms, factories, slaughter houses, wet market, health care facilities, veterinary care facilities **(S)**[18]	• Standards for antibiotic residues in effluent and solid waste from industries, sewage treatment plants, farms, health care facilities, processing units, slaughter houses **(S)** • Standards on microbial quality for effluent and solid waste discharge from farms, industry, meat processing, slaughter house, health-care facilities **(S)** • Policy on Extended Producers Responsibility for expired antibiotics **(S)**	• Assessment of situation/ knowledge on residues and AMR bacteria in effluents &wastes for policy making and regulations **(S)** • Programme for developing and promoting innovation in environmental monitoring **(S)**
	Implementation tools- Infrastructure/ Capacity/ Systems/ Resources	• Regulatory system for enforcement of laws, ensuring compliance with adequate funding and capacity **(M)** ○ Small producers to be facilitated through required measures • Tool for environmental risk assessment for siting, registration and renewal of antibiotics **(S)**	• Regulatory system for enforcement of laws, ensuring compliance with adequate funding and capacity **(M)** • Adopt progressive pathways to improve management **(S-M-L)** • Develop incentives and disincentives for compliance including performance benchmarks and rating system (such as through pond and farm	• Standard Operating Procedures (SOPs) on waste management for industries, sewage treatment plants, farms, health care facilities, processing units, slaughter houses, wet market, feed manufacturers **(S)** • Regulatory system for enforcement of laws, ensuring compliance with adequate funding and capacity **(M)**	• Development and adoption of test protocols **(S)** • Research on waste treatment technology with respect to resistant bacteria, genes, pharmacologically active substances **(S-M-L)** • Research on transmissions pathways of AMR among different environment compartments including human,

[16]Farms here mean livestock, horticulture, crops, orchards, apiculture, aquaculture

[17] Details for environmental monitoring has been included within the surveillance framework: section 3.2

[18] Related OIE and CODEX documents could be referred

		THEMATIC AREAS			
		Registration/Licensing (based on environment risk assessment)	**Biosecurity/Sanitation & Hygiene/Good Manufacturing Practices**	**Waste Management**	**Research**
			health cards) **(S)**		animal and agriculture for prioritizing intervention **(S-M-L)** • Cost-benefit analysis to assess socio-economic implications of antibiotics use **(M)** • Documentation of best practices **(M)**
	Advocacy / Awareness and Education/ Training/ Curriculum	• Sensitise regulators, industry and farmers **(S)** ○ Inclusion of environment management in antibiotics awareness week • Build capacity of regulators **(S)** • Development of customised material for awareness and training **(S)**	• Training and hand-holding on biosecurity **(S)** • Sector-specific manuals and guidelines on progressive management pathways to improve environment management **(M)** • Inclusion of biosecurity in farmer-field school curriculum or similar such approaches **(S)**	• Stakeholder training on waste management guidelines and SOPs **(S)**	• Survey of existing knowledge, attitude and practice at ground level **(S)** • Stimulation of international collaboration on research related to AMR **(M)**
	Record keeping/ Database generation/ Collation/ Dissemination and Research/ Survey	• Public database of licensed farms, factories, human and veterinary healthcare settings **(S)**	• Database on biosecurity compliance performance/ rating system (depending on local circumstances decision on public disclosure can be made) **(M)**	• Online database on waste discharge quality, rating system, compliance/non-compliance **(M)**	• Centralised database on ongoing research/ research output **(S)** • Sharing data on an international platform (for e.g., Global Environment Monitoring System) **(S-M-L)**
	Review / Monitoring / Feedback[19]	• Comprehensive review framework for policy/regulations and standards **(S-M-L)**	• Review of progressive pathways to improve biosecurity management **(S-M-L)**	• Development of success/failure indicators/milestones as part of review framework **(M)** • Compliance status with review framework **(S-M-L)**	• Review of research agenda for future policy and practice **(S-M-L)**

[19]Review as per integrated surveillance mechanism; Member countries to decide frequency and mechanism of review or monitoring

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