Food and Agriculture Organization of the United Nations

ANTIMICROBIAL RESISTANCE POLICY REVIEW and DEVELOPMENT FRAMEWORK

A regional guide for governments in Asia and the Pacific to review, update and develop policies to address antimicrobial resistance and antimicrobial use in animal production

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BACKGROUND

Antimicrobial resistance (AMR) threatens human and animal health, development and security as related infections are projected to increase. Life threatening infections that were previously manageable are poised to be untreatable because of AMR. Without action, by 2050 the global economy may lose more than USD 6 trillion dollars annually because of AMR – nearly 4% of Gross Domestic Product (GDP) (Adeyi, 2017). By 2030, 24 million more people may be forced into extreme poverty because of AMR, many will come from low-income countries. Thus, this will increase the number of people going hungry and suffering from malnutrition (Adeyi, 2017).

Consequences of AMR are much felt in low-income countries as the burden of infectious diseases make these countries more vulnerable to hardships. This puts the achievement of Sustainable Development Goals in peril. Resistant bacteria cross borders; AMR is a global problem that requires a global 'One Health' solution. Changes in agricultural production practices can help keep antimicrobials working.

Addressing the rising threat of AMR requires a holistic and multisectoral (One Health) approach because antimicrobials used to treat various infectious diseases in animals may be the same or be similar to those used in humans. Resistant bacteria arising either in humans, animals or the environment may spread from one to the other, and from one country to another. AMR does not recognize geographic or human/animal borders.

The Food and Agriculture Organization (FAO), World Organisation for Animal Health (OIE) and the World Health Organization (WHO), the Tripartite partnership, take collective action to minimize the emergence and spread of AMR. A Global Action Plan (GAP) on AMR has been supported with a strategic action plan on AMR. The Tripartite partnership has been leading the global campaign on AMR and initiated country self-assessments on AMR[1] to monitor progress with implementing their National Action Plan (NAP) on AMR (WHO, 2017). The Tripartite encourages a multi-sectoral involvement.

The United Nations General Assembly (UNGA) has recognized AMR as a global priority health issue. It is an unprecedented move, as AMR became just the fourth global health issue that the UNGA formally addressed.

The FAO is at the forefront of the campaign to mitigate AMR especially in the food and agriculture sectors. It is leading in assisting member countries in the development of their national action plans and implementing innovative public awareness and surveillance approaches in livestock production, aquaculture and crop farming.

[1] https://www.who.int/antimicrobial-resistance/global-action-plan/AMR-self-assessment-2017/en/

One of the key focus areas of the FAO action plan on AMR is strengthening governance related to antimicrobial use and AMR in food and agriculture. There are challenges in addressing AMR through government policies because of limited political commitment, low awareness and weak engagement among stakeholders. Often governments have limited capacity to implement policies because of limited technical capacity and financial resources. These are some of the reasons that this initiative has been conceptualized.

It is envisaged that this regional policy review framework addresses the challenges mentioned by offering practical guidance to government authorities, policy-makers and other stakeholders to systematically identify, assess and strengthen AMR and antimicrobial use (AMU) policies. The Framework is designed to help countries review their own national policies and provides examples from countries that facilitate effective national response to AMR.

Strengthening AMR and AMU policies is just one of the many fronts that we need to address to proactively tackle AMR. We strongly welcome the development of this policy framework that we hope you will find very useful.

ACKNOWLEDGEMENTS

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EXECUTIVE SUMMARY

Antimicrobial resistance (AMR) is a long-standing global health concern. It has recently gained political and policy momentum, particularly after the agreement of WHO member states to develop National Action Plans to address AMR (OECD, 2016; WHO, 2017; O'Neil, 2016). Significant challenges in addressing AMR through policy often include limited political commitment and low awareness and engagement among stakeholders (Dar et al., 2016; OECD, 2016). Often governments have limited capacity to implement policies because of technical capacity and financial resources gaps (FAO, 2014). This Policy Review and Development Framework is for government, policy-makers, officials, and other stakeholders in AMR and AMU policy for food-animal production within a One Health approach. It offers a practical guide for countries to systematically identify, assess, and strengthen AMR and AMU policies. The Framework is designed to help countries review their national policies and provides examples from countries that facilitate effective national responses to AMR.

The Framework can be used to identify existing policies, such as strategies and guidelines, as well as some, but not all, accompanying legislation that address AMR. For a comprehensive discussion on the legislative response to AMR, the reader is referred to the FAO document on the "Methodology to analyse national legislation relevant for AMR". This Framework's review process helps reveal gaps in national AMR and AMU policies and can help assess the compatibility of various types of national policy with international standards for addressing AMR. The primary focus of the Framework is on policies for which national authorities are typically responsible and provides insights into ways that government agencies responsible for addressing AMR can improve their policy approach to ensure that interventions are well-justified, timely and effective. A special emphasis of the Framework is given to stakeholder engagement and multi-sectoral coordination. The Framework raises questions and makes recommendations for addressing specific policy issues and provides case studies of policy interventions which can be adapted to fit various national contexts.

SECTION 1:

PURPOSE OF THE AMR POLICY REVIEW AND DEVELOPMENT FRAMEWORK

This Framework helps government policy-makers and officials identify and assess national policies related to antimicrobial resistance (AMR) and antimicrobial use (AMU) in food-animal production. The Framework is designed to guide the review of national policies to better understand existing policy that can address AMR and reveal gaps in policy. The Framework also provides examples of policy actions that countries can use, where necessary, to institute more effective AMR response and control. Criteria on AMR policy are provided for countries to consider such as stakeholder engagement in policy implementation and creation. Further, strengthening regulatory frameworks is an important step following a policy review for all countries to improve AMU and address AMR interventions. Generally, strengthening involves updating, reforming, or creating new policy and associated legislation, guidelines and directives, although as mentioned above, this publication does not go into detail on the legislative response to AMR. A review of existing national policies is important to ensure that new policies do not duplicate existing policy or similar ongoing work. When conducting the review, users should consider whether a new policy needs to be created or if the issue can be addressed by improving implementation or enforcement of existing policy. The Framework is organized into seven sections. Users should first read the entire document in sequence. Once a policy review is underway, individual sections can be used as needed, depending on the status of the review.

This Framework guides reviewers in:

- Assessing existing policies (strategies, guidelines, etc.) that address AMR and AMU;
- Determining the compatibility of existing policy with international standards and practices;
- Identifying gaps in existing AMR and AMU policies
- Recommending improved national policy response.

Overview of the Framework

Section 1 introduces the purpose.

Section 2 orients the reader to AMR and AMU generally.

Section 3 presents policy domain areas and provides questions and issues for review of national AMR and AMU policies. This process allows the user to categorize any gaps in existing policies and identify areas where policies should be developed.

Section 4 provides examples of countries in various contexts and their policy response.

Section 5 presents policy considerations and recommendations for future national policy response.

Section 6 briefly describes the steps for strengthening AMR policy and tailoring action to fit a national context.

Section 7 presents a brief conclusion.

Who should use this Framework?

The primary audience for this Framework is decision-makers with responsibility for reviewing, developing or implementing national policies to address AMR as well as technical staff with the ability to influence, develop and implement policies. The Framework examines critical AMR and AMU policy issues that need to be addressed by, or of interest to stakeholders including veterinarians, animal health workers, farmers, agricultural workers, pharmacists, government staff and quality assurance bodies. The Framework may also interest government representatives, international organizations and aid agencies and non-governmental organizations.

How was the Framework developed?

Several strategic policy actions have been proposed to mitigate, prevent and control AMR in humans and animals. In 2011, WHO World Health Day was dedicated to AMR and a policy package to address AMR was released. This package outlines six priority areas where action is needed for countries to adequately address AMR. In May 2015, the World Health Assembly in coordination with the World Organization for Animal Health (OIE), and the Food and Agriculture Organization (FAO) adopted a Global Action Plan (GAP) on AMR. The GAP outlines specific recommendations to prevent and decrease the spread of AMR.

A recommendation supported by the GAP is the development of country-specific AMR national action plans and taking a One Health approach. WHO member states agreed to develop their own national action plans (NAP) by May 2017. As of September 2017, 52 percent of countries had a fully developed NAP that takes a comprehensive One Health approach (Wellcome, 2017).

Although the creation of national action plans was a recommendation of the GAP, benchmarks for specific policies to address AMR and AMU in food and agriculture have not been identified from this strategy or from other guidance documents. Policy is an essential component for addressing AMR and AMU and helps countries codify their NAPs into legislation. Documenting and identifying benchmarks for policy focused on AMR and AMU in food-animal production is important for developing effective NAPs and improving regulatory frameworks. Besides the GAP, other guiding tools and documents provide criteria and guidance for effective strategies. In 2016, FAO released an Action Plan on Antimicrobial Resistance focusing on animal health and production, including terrestrial and aquatic animals, crop production, food safety and legal aspects and standard setting.

The FAO Action Plan supports the GAP's five strategic objectives and expects that both FAO member states will address AMR concerns. Additional tools and guidance documents reviewed include the Global Health Security Agenda and Antimicrobial Resistance Action Plan, the International Health Regulations Joint External Evaluation Tool, the OIE Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials (2016), and the WHO Manual for Developing National Action Plans. These documents and others were used to establish benchmarks for effective policy actions and guidelines for addressing AMR and AMU in food-animal production at the national level.

A workshop was held in July 2017 in Bangkok, Thailand to gather stakeholder feedback to validate and refine the Framework. The workshop brought together policy-makers and technical staff from the animal and agriculture public sectors from over 14 countries in South and Southeast Asia. Policy considerations and questions with at least some evidence to support them were presented and discussed during the workshop. Participants reviewed and discussed the Framework and its potential implementation at a national level. Feedback generated during this workshop was used to build on and enhance the Framework.

How is policy defined in this Framework?

In this Framework, 'policy' is used generally to refer to strategies, codes of practice, guidelines and quality assurance programs, while legislation refers to legally binding instruments (including both primary and secondary legislation), as defined by each country. A key difference for the reader to keep in mind is that only legislation is enforceable. All types of policy can and should be used to directly or indirectly outline interventions to mitigate AMR, including AMU controls. Table 1 defines the terms discussed in this Framework.

Table 1. Definition of key terms.

Term	Definition
Policy	• FAO defines policy as the "stated objectives that a government seeks to achieve and sustain a decision or a set of decisions made by individuals, organizations, or governments that are oriented toward addressing a topic or issue." • Public policy guides government actions in the management of public affairs such as protecting animal and human public health.
Legislation	• Legislation refers to any legally binding instrument as promulgated or enacted by the competent national authority. For example, laws and regulations are pieces of legislation. In this document, "legislation" includes both, primary and secondary legislation. • "Primary legislation" refers to legally binding instruments, which are normally enacted by the legislative branch of the State (Parliament) or the authority with such power according to national legislation. • "Secondary legislation" refers to legally binding instruments promulgated pursuant to primary legislation, by the authorities delegated the powers to do so. Secondary legislation typically provides detail and specificity for the implementation of primary legislation.
Strategy	• A strategy is a detailed description of how a policy will be implemented to achieve its stated goals. • Examples of AMR strategy include National Action Plans to address AMR.
Regulatory Framework	• A regulatory framework refers to all national instruments that may have regulatory implications, including national policies, strategies, the institutional framework and legislation. • Agencies, such as a Ministry of Agriculture or Health, are responsible for implementing components of a regulatory framework.

Given the multidimensional nature of AMR, policy options to address it fall into two categories.

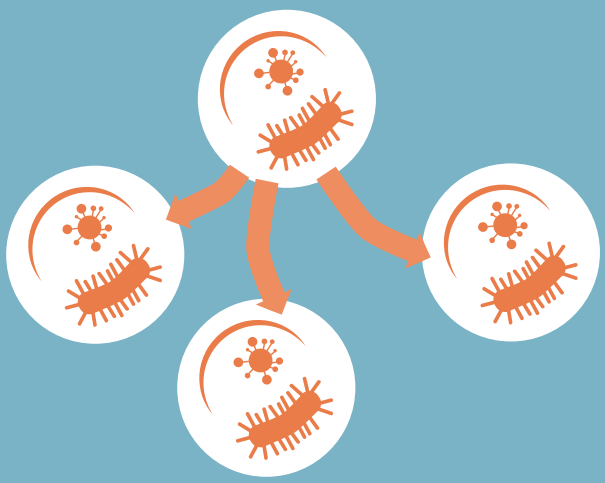
Both are considered in this Framework.

1. **AMR-specific policies:** Policies created to limit the development or spread of AMR (i.e. National Action Plans). These policies typically state that they address AMR.
2. **AMR-related policies:** Policies adopted for reasons other than to address AMR (e.g. policies on livestock development or for promoting aquaculture), however, they have an indirect impact.

Steps to consider when conducting a policy review using the Framework

When countries conduct a policy review to better understand national AMR policy response, the following steps should be taken:

- Establish and explain the purpose of the policy review.
- Identify policies and collect information to answer the questions posed in Section 3 of the Framework.
- Identify and describe policy gaps, barriers to implementation of policies and enforcement of legislation and opportunities to improve national actions.
- Make recommendations based on the findings in the steps above. Recommendations should also describe the national context including social, economic, and political considerations that may influence the policy environment. An example of questions to answer is included in Section 3.



SECTION 2:
OVERVIEW OF ANTIMICROBIAL RESISTANCE

AMR poses a global health risk to the effective prevention and treatment of many animal and human infections caused by bacteria. AMR occurs when bacteria acquire resistance genes that enable them to survive in the presence of antimicrobial agents including antibiotics (WHO, 2015). With extensive global trade and travel, antimicrobial-resistant bacteria can spread quickly throughout the world leaving no country invulnerable. Drug-resistant bacteria are estimated to cause 25,000 deaths in Europe annually and with resistance prevalence rising many infectious diseases may one day become untreatable (ECDC, 2009). Without effective interventions, such as policy changes, AMR associated human mortality is expected to increase from 700,000 global deaths in 2014 to over ten million by the year 2050 (O'Neill, 2016).

AMR affects high and low-income countries, and estimates indicate that AMR will cause an increase in extreme poverty and a disproportionate impact on the economies of low-income countries (World Bank, 2016). Immediate AMR concerns are similar across low- and middle-income countries and also pose threats to livestock and food security. The impact of AMR on morbidity and mortality is matched by a substantial economic burden. AMR is anticipated to cause losses that exceed USD 100 trillion annually by 2050. The United States Centers for Disease Control and Prevention (CDC) estimates that in the United States of America alone, the annual impact of antibiotic resistant infections on the economy is USD 20–35 billion in excess health care costs (CDC, 2013).

The emergence and spread of AMR bacteria are influenced by antimicrobial use in humans and food animals. Inappropriate use, including misuse and overuse, of antimicrobials in humans, food animals and crop production accelerate the rate at which AMR is occurring. Increased use of antimicrobials in food-animal production is a significant concern for potential spread of AMR bacteria into the environment and to humans (Hershberger et al., 2004). In some countries, antibiotics are widely used in healthy food-producing animals for non-therapeutic purposes such as to promote feed efficiency or rate of weight gain. This practice favours the emergence and spread of resistant bacteria in food animals and into human populations. Resistant microorganisms carried by food-producing animals can

spread to humans through consumption of contaminated food, direct contact with animals, or through the environment, for example in contaminated water. For most human cases of AMR bacterial infections, we do not know to what extent the resistance was initially generated or acquired from food-animal populations, humans, or the environment.

Policy review process

To respond effectively to AMR and associated AMU controls, a review of national policies should accompany national actions and responses within a country. This Framework offers insights into how policies interact and affect AMR-related outcomes. This section presents the policy domain areas and questions to guide a review of national policies that directly or indirectly address AMR. The process allows the user to identify gaps in existing policies that need to be addressed and is only one part of the process for improving policy response.

The Framework recommends a three-step policy review process:

Step 1: Examine general indicators to understand the country context. Example indicators are provided below. However, additional indicators should be used depending on the national context and the information available.

Step 2: Review national policies based on the policy domains outlined in this Framework. A list of questions is provided.

Step 3: Analyze the findings and draft recommendations. Recommendations can be informed by the policy recommendations and considerations provided in *Section 5.*

Users of the Framework should:

- Select and extract relevant policy information from national policy databases and other sources.
- Produce responses to the proposed questions.
- Compile results into a final report with recommendations for action.

Step 1: Examine the country context

1.1 National regulatory framework

To describe the national regulatory framework, users can provide background on recent policy actions, review political commitment and describe stakeholder contributions in addressing AMR. To better understand the policy environment, users should include an overview of the government authorities that will create and implement policy related to AMR and AMU in food animals. A description should be included of the entities relevant to overseeing implementation of policies.

1.2 Agricultural, social, and cultural indicators[2]

Users of this Framework should answer the following questions. If available, recent information and data regarding these questions should be included in the review.

1. Population size (by all available administrative levels)
2. Population growth rate
3. Population density
4. Poverty:
   a. Proportion of entire population below the national poverty line
   b. Proportion of population living in poverty whose primary income is from agriculture
5. Percent of employment in agricultural sector and proportion in food-animal production
6. Income
   a. Per capita income
   b. Average estimated income of smallholders, large producers, food-related occupations
7. Annual growth rate of the agricultural sector
8. Structure of veterinary pharmaceutical distribution and retail systems (e.g. feed mills, distributors, direct sales)

[2] Gender should be considered where appropriate.

9. Food-animal production systems
    a. Number and location of farms (e.g. smallholders to large production facilities)
    b. Food animal types
    c. Typical flock, herd or other group sizes
10. Agricultural outputs, with emphasis on foods of animal origin (domestic and export)
11. Number of veterinarians, paravets, and other animal production caretakers
12. Number of veterinary education programs and number of veterinarians graduating annually
13. Size, capacity, capability, and number of animal health laboratories
14. Information on slaughter and processing facility capacity

Step 2: Policy review

There are four domains in which AMR and AMU policy can be examined: awareness, evidence, practices and governance. These policy domains were identified from overlapping themes in the FAO action plan. Each policy domain focuses on specific components and objectives of an effective national AMR response. Awareness and education regarding AMR are aimed at initiatives to increase awareness among stakeholder groups. Evidence includes surveillance and monitoring AMR and AMU of antimicrobials in food animals. The Practice domain reviews efforts for responsible use that should reduce or restrict the use of antimicrobials in food animals. Governance discusses how institutions and authorities control AMU and AMR and how to integrate stakeholders across jurisdictions and disciplines. Figure 1 illustrates how these four policy domains overlap.

FIGURE 1. POLICY DOMAINS FOR NATIONAL AMR POLICY RESPONSE.

In the next section, the four policy domains will be further explained and a set of questions and criteria for countries to consider is presented for reviewing policies under these domains. When reviewing policies, questions can be answered according to the following status categories:

Status category A: Existing

Subcategories:

1. Existing and fully implemented
2. Existing but only partially implemented
   a. Needs revision (e.g. amendments are needed, updating)
   b. Needs further support (e.g. financial support, more effective enforcement, human resources)
   c. Needs revision and further support
3. Existing but not implemented
   a. Not implemented due to lack of advocacy, training, awareness, resources, legislation, feasibility, accessibility or relevance (include options for this response)

Status Category B: Not existing

Subcategories:

1. Not existing and need to be established
2. Not existing but being developed
3. Not existing and not needed or prioritized

Status Category C: Not applicable

Subcategories:

1. Not applicable to the national context (i.e. lack of resources or not feasible)
2. Not applicable due to other reasons (please specify)

The status categories can be used to identify areas of strength and weakness and should inform the development of a set of recommendations to be used in the final report described in Step 3.

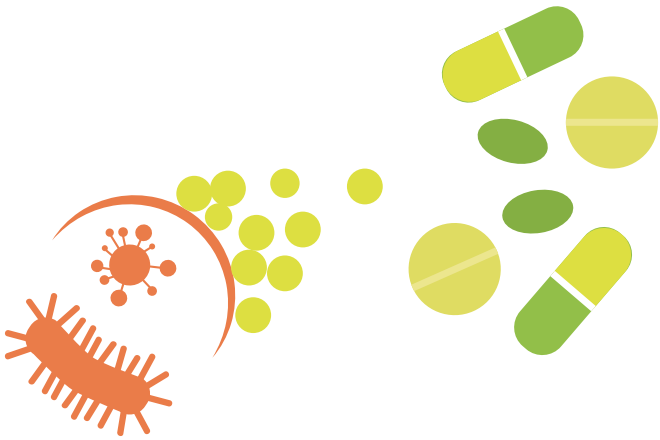

GOVERNANCE

SECTION 3:
QUESTIONS TO GUIDE THE POLICY REVIEW

Policy Domain 1: Awareness

Raising awareness among stakeholders and educating professionals and the public are essential to combatting AMR. 'Awareness' is a policy area as it is linked to all other policy domains and is critical for implementing AMR initiatives. Education and awareness campaigns and training and curriculum should target different audiences, including antimicrobial prescribers, farmers, pharmacists, veterinarians, and the general public.

Levels of knowledge and awareness vary substantially across countries and stakeholders typically have limited knowledge or awareness of appropriate antibiotic use or the causes of antimicrobial resistance (FAO, 2016; WHO, 2015; Dar et al., 2016). Governments should ensure that mechanisms are in place for stakeholder engagement and that awareness raising events use evidence-based practices and events are designed to achieve policy objectives. Within this context, governments should respond to these questions to assess existing and planned policies related to AMR awareness and education.



Questions under Policy Domain 1: Awareness

Subdomain	Policy questions		Status
General population	1.	Has the government established policy to increase awareness of AMR among the general public?	
	A	If yes, does policy support participation in national, regional or global awareness raising events (e.g. World Antibiotic Awareness Week)?	
	B	Are goals and objectives for awareness raising initiatives described in policy?	
	C	If yes, has an assessment, monitoring and evaluation mechanism been established for assessing attainment of these goals?	
	D	Does the government monitor and assess the objectives, costs, and success of awareness raising initiatives?	
	E	Do strategies to address awareness raising include a timeline for achieving goals and objectives?	
Animal, aquaculture and environment workforce	2.	Has policy been established that includes AMR and related topics in continuing education programs focused on veterinary, livestock, aquaculture, the environment, and training outside formal academic settings?	
Academic settings	3.	Has the government established policy that includes AMR and related topics?	
	A	In primary and secondary school settings?	
	B	In undergraduate and graduate curricula, such as veterinary medicine?	
	C	In postgraduate curricula?	
	4.	Does policy advocate to include AMR education and related topics in extracurricular activities in school settings?	
Training	5.	Does a department or ministry prepare trainers for education and awareness raising initiatives?	

Subdomain	Policy questions		Status
General considerations when reviewing policies to address awareness and education initiatives	6. Does policy describe measures taken by the government to ensure the quality of materials used in awareness raising initiatives? For example, requiring evidence-based approaches be used or that materials reflect the local and national contexts (e.g. local language and tailored to local and national norms)?		
	7. Are policies related to awareness raising and education and their implementation clearly written, transparent, and readily accessible and appropriate for the target audience (e.g. the implementing agency is defined)?		
	8. Has a department or ministry been delegated to implement and oversee awareness raising activities at a national level?		
	A	If yes, is the development of awareness raising resources or activities part of the formal job description of the designated ministry or department?	
	B	If yes, what authority do the designated staff have over the adaptation and use of awareness raising resources for different contexts?	
	9. Is government funding allocated for implementing your country's awareness raising or education activities? Is funding sufficient for full implementation of activities?		
	A	If no, is financial or in-kind support provided by development agencies, development banks, foundations or other non-public funding bodies for awareness raising and education initiatives?	
	10. Has the government allocated appropriate and sufficient resources for awareness raising activities beyond financial support including human resources, materials and training?		

Subdomain	Policy questions		Status
Stakeholder engagement for increasing awareness on AMR	11. Have potential stakeholders for AMR awareness raising activities and education initiatives been identified?		
	12. To what extent do current policies motivate stakeholders to implement and participate in AMR awareness raising initiatives (e.g. mandates, financial and human resource allocation)?		
	13. Have processes been identified that are already in place to engage stakeholders in AMR awareness raising among stakeholder groups and by level (i.e. local, regional and national)?		
	A	If yes, are these processes being used to engage stakeholders (e.g. workshop on disseminating AMR-related education provided to stakeholders involved in broadcasting AMR information)?	
	14. Are mechanisms in place to enable stakeholders to participate in the design and implementation of education and awareness campaigns and events?		
	A	Specific to graduate and undergraduate curricula?	
	B	Specific to continuing education training outside formal academic settings?	
	C	Specific to the general population?	
	15. Are mechanisms established for coordination between sectors on AMR awareness raising activities when appropriate?		
	16. Does the government have a system or mechanism for exploring the gaps and needs of different stakeholders regarding AMR awareness and education?		

Potential stakeholders in awareness and education policy

General public, animal feed producers and sellers, consumer groups, farmer associations, implementing ministries, drug stores (pharmacies), pharmacists, private and public veterinary clinics, development partners, teachers, students, drug importers, animal food producers, veterinarians, animal health practitioners, policy-makers, members of parliament and legislatures.

Whatever approach a government adopts to increase national awareness and knowledge on AMR, complementary measures can help ensure policies are consistent with domestic priorities. All relevant ministries should be involved in the policy development process to ensure that all parts of government are aware of commitments and to help identify and resolve potential conflict between those commitments and domestic legislation. For example, policy that describes efforts to increase AMR awareness in undergraduate and graduate level education should involve the Ministry of Education. As in all policy areas, governments should consult widely with stakeholders and establish AMR awareness and education goals supported by clear and measurable targets. Policy goals should be achieved through education programs, advertising campaigns, workshops and training events, and other interventions. Reports describing progress toward addressing goals should be compiled by the implementing authorities, publicly disseminated and shared with policy-makers and legislators.

Policy Domain 2: Evidence

Policies and legislation on notifiable diseases and other infectious disease reporting provide the framework for countries to implement surveillance and monitoring systems. Documenting resistance through surveillance, monitoring and research provides essential information for improving national policies. Reliable data are essential to assess the sources of AMR, to conduct a risk assessment process and to evaluate the impact of mitigation measures. Generating and understanding evidence on AMR and AMU at a national level is important for monitoring reductions and understanding the impact of policy and focusing future interventions. Research can help reduce excessive and inappropriate antimicrobial use and identify areas of concern. Data on use of antimicrobials in animals is needed for risk profiling, risk assessment and research purposes and for setting risk management goals and evaluating their effectiveness.

There are several ways governments can use the regulatory framework to build an evidence base on AMR and AMU. Legislation play an important role in establishing social and business norms around disease surveillance. Policy should be established that promotes regular dissemination of data to policy-makers to inform national actions. National evidence priorities can be described along with the expected roles of different groups. Policy and national strategies can help build consensus between stakeholder groups regarding evidence priorities. Additionally, policy can help to ensure that adequate resources are allocated to support activities to build an evidence base. Currently, FAO is supporting countries to provide OIE with data on import, national sales and distribution of antimicrobials (OIE, 2017). FAO aims to support countries in developing methodology for data collection at the farm-level.

Countries should consider the following criteria and questions when reviewing national policies intended to expand the evidence base. While the criteria include certain aspects of legislation where legal underpinnings are necessary, this should not be taken as a comprehensive guidance for legal reform. For that, the reader is directed to the FAO publication "Methodology to analyze AMR-relevant legislation in the food and agriculture sector".

Questions under Policy Domain 2: Evidence

Subdomain	Policy questions		Status
Governance for AMR surveillance	1.	Has the government established policy on the development, implementation and maintenance of a national surveillance system for AMR pathogens in animals?	
	A	If yes, is this legislation consistent with, and does it leverage existing legislation on disease reporting or surveillance requirements?	
	B	If yes, is this system harmonized or integrated into regional or global AMR surveillance systems when appropriate?	
	C	If yes, has a clear chain of command been established and described for implementing surveillance? *	
	D	Is there any overlap in responsibilities related to surveillance between agencies or departments? *	
	E	Has authority been designated for all stages of surveillance (e.g. designing, collecting, analyzing and disseminating findings)? *	

* Appropriate legal underpinnings would be required. Please review national legislation to respond to these questions. For comprehensive guidance on legal analysis, please refer to the FAO Methodology to analyse national legislation relevant for AMR.

Subdomain	Policy questions		Status
Governance for AMR surveillance	2.	Has an agency or department been given official authority for accessing samples for surveillance? *	
	A	If yes, have appropriate legal mechanisms been established to ensure this authority? *	
	3.	Are farms legally required to provide samples for AMR surveillance, as needed? *	
	A	If yes, where are these mechanisms underpinned by appropriate legislation?	
	4.	Have coordination mechanisms between ministries been established to share surveillance findings (e.g., data sharing)? *	
	A	If yes, where are these mechanisms underpinned by appropriate legislation?	
	5.	Have guidelines for standards and protocols on surveillance been established?	
	A	If yes, do these guidelines follow international or regional standards for surveillance?	
	6.	Have resources been designated to support the development and implementation of an AMR surveillance system?	
	A	If yes, are resources sufficient to support ongoing surveillance activities?	
Governance for AMR and AMU monitoring	7.	Have requirements been established for specific agencies to monitor AMU in animals and agriculture? *	
	A	If yes, is there a requirement for the designated agencies to report data related to AMU? *	
	8.	Does legislation require recording and reporting sales data of antimicrobial products? *	
	A	If yes, have mechanisms been established to ensure its implementation? (e.g. legal mechanism, clear assignment of responsibility, designated agencies)? *	

* Appropriate legal underpinnings would be required. Please review national legislation to respond to these questions. For comprehensive guidance on legal analysis, please refer to the FAO Methodology to analyse national legislation relevant for AMR.

Subdomain	Policy questions		Status
Governance for AMR and AMU monitoring	I. If yes, is it clear what information needs to be recorded and who is responsible for collecting this information? *		
	II. If yes, has an authority been designated to interpret and disseminate this data? *		
	III. How is the enforcement supported? (e.g. penalties are described, an enforcing agency has been identified)? *		
	9. Have standardized guidelines for interpretation of measurements been described in policy for monitoring systems for AMR and AMU?		
	A	If yes, do these guidelines rely on international or regional standards?	
	10. Have coordination mechanisms been established to share monitoring information between human and animal sectors? *		
	11. Has policy been established to support monitoring drug quality with a focus on reducing use of substandard and counterfeit drugs?		
	12. Have coordination mechanisms been established at the local, national, regional and global levels for information sharing related to monitoring activities?*		
	13. Has policy or legislation been established that requires monitoring the use of antimicrobials at the food-animal production level? *		
	A	If yes, has legal authority been granted so that retailers, veterinarians, animal producers, or other relevant stakeholders are required to provide this information? *	
	14. Have guidance or procedures been established that describes the use of monitoring data for risk assessment?		
	15. Has legislation been established that requires testing for veterinary medicinal product residues in foods of animal origin? *		

* Appropriate legal underpinnings would be required. Please review national legislation to respond to these questions. For comprehensive guidance on legal analysis, please refer to the FAO Methodology to analyse national legislation relevant for AMR.

Subdomain	Policy questions		Status
Laboratory infrastructure and operations	16. Does policy describe allocation of sufficient human resources to support laboratories for surveillance and monitoring activities?		
	17. Is there policy support for laboratories to isolate and identify bacterial isolates?		
	18. Is there policy support for laboratories for performing antimicrobial susceptibility testing?		
	19. Does policy describe allocation of sufficient financial resources to support laboratories for surveillance and monitoring activities?		
	20. Is the approval of laboratory standards underpinned by legislation? *		
	A	If yes, should these be informed by international standards?	
	21. Is there a policy promoting standardized laboratory protocols and quality assurance?		
Research	22. Has the government established policy or legislation to support research on AMR and AMU?		
	A	If yes, have specific agencies been assigned a mission or duty to conduct this research? *	
	B	If yes, is this mandate consistent with existing policies requiring research on other diseases?	
	C	If yes, is this research informed by national or international research priorities on AMR?	
	D	If yes, have resources been allocated or designated to support research activities?	
	E	If yes, is there a policy that requires disseminating research findings?	
	6. Is there a policy promoting standardized laboratory protocols and quality assurance?		

* Appropriate legal underpinnings would be required. Please review national legislation to respond to these questions. For comprehensive guidance on legal analysis, please refer to the FAO Methodology to analyse national legislation relevant for AMR.

Subdomain	Policy questions	Status
Stakeholder engagement for building the AMR/AMU evidence base	23. What procedures and institutions have been established to ensure that stakeholders can participate in, and be sufficiently informed about surveillance, monitoring and research related to AMR and AMU?	
	24. What measures has the government taken to engage stakeholders on policy decisions related to building the AMR and AMU evidence base including policy development for research, surveillance and monitoring?	
	25. Has the government established mechanisms to share findings from evidence activities at a regular interval to the general population?	
	26. Has a national focal point been designated for maintaining contacts with stakeholders such as clinicians, epidemiologists and pharmacists on AMR evidence building activities?	

Potential stakeholders in evidence gathering and use

Private companies, drug retailors, implementing ministries, farmers and animal producers, epidemiologists, microbiologists, national animal health authorities, laboratory staff, policy makers, international organizations, universities, local NGOs, research institutions, researchers, research institute funding agencies, universities, authority agencies.

Policy Domain 3: Practices

In this Framework, practices related to AMR and AMU include responsible use practices to reduce or restrict the use of antimicrobials in food animals.

These are interventions at the production level that reduce the risks of diseases developing on the farm such as providing good housing and management, correct nutrition as well as biosecurity[3]. Examples of biosecurity measures include infection prevention and control such as cleaning and disinfection, vaccination, and animal movement management. Effective infection prevention and control is critical for reducing antimicrobial use in animal husbandry and limits the development of drug-resistant strains (O'Neill, 2016). Husbandry factors that contribute to AMR include poor biosecurity measures such as lack of disinfection, inadequate pen cleaning and practices that promote stress on animals (e.g. transport of animals, stocking density). For infection prevention and control policy, there need not be an AMR-specific policy intervention and the absence of specific policy interventions should not be considered a gap or a deficiency.

Targeting the distribution of antimicrobial products is particularly important for addressing misuse and overuse in animals. An appropriate regulatory framework would be an effective method to promote more appropriate use of antimicrobials. The regulatory framework designed to minimize and limit the spread of AMR in the environment should include considerations regarding the antimicrobial manufacturing and effluent discharge standards for manufacturing industries. Best practices and industry standards can be adopted to ensure safe and sustainable husbandry practices are implemented, thereby minimizing the spread of AMR in the environment. While the table below include certain aspects of legislation where legal underpinnings are necessary, this should not be taken as a comprehensive guidance for legal reform. For that, the reader is directed to the FAO publication "Methodology to analyze AMR-relevant legislation in the food and agriculture sector".

[3] Means a set of management and physical measures designed to reduce the risk of introduction, establishment and spread of animal diseases, infections or infestations to, from and within an animal population (OIE, 2018).

Questions under Policy Domain 3: Practices

Subdomain	Policy questions	Status
Infection prevention and control	1. Has the government established standards or guidelines related to infection prevention and control specific to the animal health sector? *	
	A If yes have these documents been updated in the last five years?*	
	B If yes, do these guidelines follow international or regional standards or guidelines (e.g. Codex standards, FAO standards)?*	
	2. Have biosecurity guidelines been established for different farm production systems?	
	3. Has policy been established that specifies national participation in regional infection control networks?	
	4. Does legislation describe any training requirements for animal health specialists (veterinarians etc.) or other animal health worker types (e.g. community animal health workers) specific to infection prevention and control?*	
The environment	5. Is there legislation in place that require manufacturers of antimicrobials to limit emission of substances that cause harm to human and animal health and the environment including the discharge of antibiotic manufacturing wastes or residues into water and land?*	
	6. Is the environment recognized or acknowledged in policy as an important pathway to consider in preventing and controlling the spread of AMR?	

* Appropriate legal underpinnings would be required. Please review national legislation to respond to these questions. For comprehensive guidance on legal analysis, please refer to the FAO Methodology to analyse national legislation relevant for AMR.

Subdomain		Policy questions	Status
The environment	7.	Is there legislation in place that limit or restrict emission of antimicrobials into the environment from farm waste, including animal waste disposal and transport of animal wastes by water runoff? *	
	A	If yes, are criteria established regarding antimicrobial manufacturing practices including design, monitoring, and control of manufacturing processes?	
	8.	Has legislation been established that prohibits or restricts the use of antimicrobials as pesticides in any way?*	
Regulation of antimicrobials	9.	Does legislation define the legal use of antimicrobials in animals and agriculture?*	
	10.	Has legislation been established that describes quality standards in the production, import and export of veterinary medicines?*	
	11.	Has legislation been established to restrict the use in animals of medically important antimicrobials?*	
	12.	Has legislation been established to eliminate, reduce or restrict the use of antimicrobial products for production efficiency and to provide risk criteria for diagnosis for disease prevention uses in animals and agriculture?*	
	A	If yes, are these pieces of legislation consistent between animal feed requirements and direct administration? If no, explain.*	
	13.	Has the government established legislation that describe prescription practices (or an equivalent mechanism) for antimicrobial use in food animals?*	
	A	If yes, is a prescription required for antimicrobial use in food animals?*	
	B	If yes, does legislation clearly describe who can provide a prescription for antimicrobial use in animals?*	

* Appropriate legal underpinnings would be required. Please review national legislation to respond to these questions. For comprehensive guidance on legal analysis, please refer to the FAO Methodology to analyse national legislation relevant for AMR.

Subdomain	Policy questions		Status
Regulation of antimicrobials	14. Has the government established legislation on antimicrobial use?*		
	A	Who has the legal authority to administer antimicrobials to food animals?*	
	B	Where can antimicrobials for use in animals be sold and to whom?*	
	C.	Who is entitled to sell or distribute antimicrobials for use in food animals?*	
	D.	Does the legislation require keeping records on the prescription, sale and distribution of antimicrobial products?*	
	E.	If yes, does this information explicitly state what information must be recorded and who collects this information?	
	15. Does legislation specify labelling requirements for antimicrobial products? *		
	A.	If yes, are language requirements described?*	
	B.	If yes, is the 'withdraw time' required?*	
	C.	Are false or misleading claims prohibited?*	
	D.	Is the antimicrobial required to specify that it is for animal use only?*	
	E.	Does the label require the status of product registration?*	
	16. Has legislation been established that specifies requirements for advertising antimicrobial products?*		
	17. Are combinations of materials (antimicrobial agents) allowed to be mixed into animal feed?*		
	18. Has the government established policy to promote antimicrobial stewardship programs or other initiatives focused on promoting responsible antimicrobial use?		
	19. Has a duty or mission been given to a specific agency to address the illegal distribution of antimicrobials?*		

* Appropriate legal underpinnings would be required. Please review national legislation to respond to these questions. For comprehensive guidance on legal analysis, please refer to the FAO Methodology to analyse national legislation relevant for AMR.

Subdomain	Policy questions		Status
Regulation of antimicrobials	20.	Has an agency or department been delegated to investigate distribution pathways for the sale of illegal drugs such as Internet sales platforms and cross-border distribution?*	
	21.	Has legislation been established to address the use of antimicrobial products in animal feed?*	
	A	If yes, does the legislation specify how combinations of materials (antimicrobial products) in animal feed are to be used?*	
Stakeholder engagement	22.	Has the government established consultation mechanisms and procedures, including public notification requirements, before enacting new national policies related to the use of antimicrobials in animals?	
	A	If yes, what are the main avenues for this communication?	
	23.	Is there clear guidance to policy-makers on how consultations should be conducted with stakeholders on policies related to using antimicrobials?	
	24.	Have mechanisms been established for the government to actively engage with stakeholders on promoting rational AMR use?	

Potential stakeholders in practices

Implementing ministries, farmers and animal producers, private companies, drug retailors, veterinary professionals, industry, epidemiologists, microbiologists, national animal health authorities, animal health workers, laboratory staff, policy makers, international organizations and partners, universities, local NGOs and research institutions.

* Appropriate legal underpinnings would be required. Please review national legislation to respond to these questions. For comprehensive guidance on legal analysis, please refer to the FAO Methodology to analyse national legislation relevant for AMR.

Policy Domain 4: Governance

Effective, efficient governance is the foundation of nearly all successful policy. This Framework takes a comprehensive approach to understanding governance by considering governance mechanisms, enabling environments, and the capacity of governance systems. Understanding how governance drives, influences and informs AMR control and prevention strategies at the national level is essential for addressing AMR. Governance mechanisms can include working groups, national bodies to handle antibiotic issues and other designated entities for AMR and AMU priority setting. AMR governance is the responsibility of each country in leading implementation in their respective country (World Bank, 2016). Governance and plans for governance can also indicate political will within countries. "Reducing antimicrobial resistance will require the political will to adopt new policies, including controlling the use of antimicrobial medicines in human health, animal and food production" (WHO, 2015, p.5). Knowing if a national body has been designated to deal with antibiotic issues is important to understanding how countries are responding to AMR and AMU.

AMR presents a health risk at the human-animal-plant-environment ecosystems interfaces and requires coordination between sectors–essentially a One Health approach. Effective national AMR response requires engagement from multiple sectors of government. Support for multi-sectoral coordination is critical. National action plans (NAPs) should include input and formal collaboration between sectors. Integrating sectors when developing NAPs gives each sector a sense of ownership in the plan (WHO/FAO/OIE, 2016).

A recommendation from AMR guidance documents is that all sectors be involved in preparing and implementing a NAP. Multi-sectoral approaches to policy design and delivery are a common objective for many public administrations as a way to integrate cross-disciplinary perspectives into policy, improve coordination and facilitate resource sharing.

Questions under Policy Domain 4: Governance

Subdomain	Policy questions		Status
Governance	1.	Have agencies responsible for developing policies to address AMR and AMU in animals and agriculture been identified?	
	A	If yes, do they have clear and well-defined responsibilities to ensure antimicrobial use planning?	
	2.	Are policies related to AMR transparent, easy to understand and readily accessible?	
	3.	Are all policies related to AMR and AMU compiled into a registry or a compendium of information?	
	4.	Is there a ministry, office or department with an explicit mission to address AMR and AMU in animals and agriculture?	
	A	If yes, is the ministry provided with guidance on the scope of this mission including a description that clarifies the scale and role in addressing AMR?	
	B	If yes, is this a permanent mission or authority or a special or temporary project?	
	5.	Has the government signed and ratified a national action plan (NAP) to address AMR at the national level?	
	A	If yes, is this plan published with open access?	
	B	To what extent has the NAP been informed by international recommendations and recognized standards. Does it align with the objectives described in the Global Action Plan on AMR?	
	6.	Have funding and resources been allocated for full implementation of the NAP?	
	A	If yes, is the funding for the NAP sourced from a regular budget or from project funding?	

Subdomain	Policy questions	Status
Governance Mechanism	7. Have mechanisms been established to coordinate efforts to address AMR at the national level across sectors and agencies?	
	A. If yes, how formalized are the relationships between sectors in relation to tactics to address AMR? (e.g., mutual aid agreements, MOUs, informal agreements, inter-ministerial declarations)?	
Enabling Environment	8. Is there an environment that creates the infrastructure for adequately implementing policies related to AMR and AMU? Specifically, are adequate resources and infrastructure provided such as laboratory capacity and workforce development?	
Capacity	9. Does the government provide human and financial resources to relevant government agencies to ensure development and enforcement of an adequate regulatory framework to address AMR?	
	10. Does the government have sufficient expertise to respond effectively to AMR? For example, does the higher education system provide skills for professionals to address AMR such as veterinarians, laboratory staff and pharmacists?	
	11. How does the government ensure nation-wide implementation of standards and legislation related to AMR and AMU?	
Stakeholder engagement	12. What measures has the government taken to engage stakeholders during policy development to address AMR?	
	13. Are consultations with stakeholders held on existing and proposed legislation on a local, regional and national basis?	
	14. Are consumer advocacy groups supported and encouraged to participate in multi-stakeholder initiatives to address AMR?	

Subdomain	Policy questions	Status
Stakeholder engagement	15. How does the government ensure legislation does not impose an unnecessary burden on stakeholders? Is there a built-in mechanism to periodically review these burdens? Are these burdens measured and quantified?	
	16. Are opportunities for public consultation well-publicized, well-organized, accessible and well-timed for new policies related to AMR?	
	16. Are opportunities for public consultation well-publicized, well-organized, accessible and well-timed for new policies related to AMR?	
	17. If a NAP has been established, was this informed by stakeholder mapping as it relates to AMR in animals and agriculture?	
	18. Are mechanisms in place for AMR information sharing among all relevant sectors and stakeholders?	
	19. How does national governance align with stakeholder groups across levels (e.g. stakeholder associations, farmers' advocacy groups, farm and organizational infrastructure)?	

Potential stakeholders in governance

Policy makers, veterinarians, animal health workers, implementing ministries, farmers and animal producers, private companies, drug retailers, national animal health authorities, pharmaceutical retailers, regulating agencies, international organizations and partners, universities, local NGOs and research institutions.

Step 3: Analyzing findings and drafting recommendations

After answering the questions in Step 2, a final report should be written that identifies areas of compliance and differences, disparities, gaps, remaining challenges, disadvantaged population groups and geographical areas, and future priorities that need to be addressed by the country's regulatory framework for addressing AMR. Depending on these findings, recommendations should be made on how to enhance the country's regulatory framework. Recommendations can be informed by guidelines provided in Section 5. These guidelines should be modified to reflect national needs and country contexts. Users of this Framework are responsible for realistically planning, coordinating, and conducting review processes and producing a final report by maximizing use of existing in-country capacities among national agencies and experts.

Example outline for the final report:

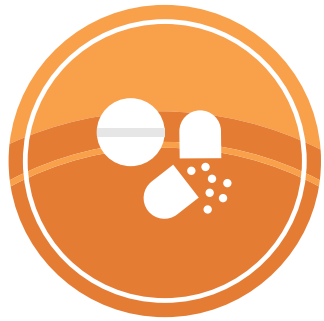
The following is an example outline for a final report to help present and organize findings developed by the review.

1. Assess the situation in each country.
    a. Country background (based on Step 1: Examining the country background).
    b. Review the regulatory framework according to indicators described in Step 2. In this part, the information should be structured around thematic areas identified by the policy domains.
2. Describe implementation of policy including successes, gaps and compliance issues.
    a. Compliance with and gaps in policy (e.g. an analysis of what is missing or could be strengthened in the country's policies and legislation).
    b. Compliance with and gaps in the policy framework and concrete implementation.
3. Make recommendations to enhance the national regulatory framework for AMR.
    a. Based on identified gaps, provide recommendations for creating and strengthening evidence-based policy informed by guidelines provided in Section 5.

SECTION 4:
EXAMPLES OF AMR POLICY

To better understand AMR policy across the four policy domains, this section describes successful policy interventions. Examples are drawn from both human and animal sectors. The unique characteristics of each intervention are described along with policy evaluation information if available. These examples demonstrate the complex nature of AMR and highlight the need for policy to be tailored to each country's context.

Examples under Policy Domain 1: Awareness



AMR public awareness campaigns and education initiatives are tailored for specific audiences. Two types of interventions addressing awareness and education have been used across countries. These include public awareness campaigns and education and training initiatives aimed at the animal health workforce. Country initiatives to increase knowledge and awareness of AMR and AMU are driven and supported by different policy types aligned with national strategies to combat AMR. For example, in Europe, a national strategy called "Communication from the Commission to the European Parliament and the Council: Action plan against rising threats from antimicrobial resistance" was released in 2011 to guide EU action in addressing AMR. This plan describes communication, education and training activities related to AMR and establishes evaluation indicators.

Since 2008, public awareness campaigns in European countries have focused on introducing the European Antibiotic Awareness Day (EAAD), which aims to raise national awareness on prudent antibiotic use among the general public. EAAD is held annually in November during World Antibiotic Awareness Week. Similar awareness campaigns have occurred in different parts of the world. The "Get Smart About Antibiotics Week" takes place every November in the United States of America. The CDC is the lead agency in planning national awareness raising efforts. However, initiatives trickle down to other federal agencies and to the state and local level.

Beyond government actions, awareness-raising initiatives in the United States of America are also driven by consumer advocacy groups through campaigns targeting specific groups, media reports, menu labels and behaviour change campaigns. Consumer advocacy organizations have demonstrated their role in shaping AMR policy by influencing consumer preferences for antibiotic-free animal products. Raising awareness among consumers in the United States of America has been credited with creating a market for antibiotic-free food products. Sales of antibiotic-free chicken increased 34 percent in 2013-2014 (NRDC, 2015). Over the past few years, members of the United States of America Antibiotic Resistance Coalition and its partners have called upon animal food producers and food retailers to make time-bound commitments to source food-animal products without the routine use of antibiotics (US PIRG, 2017). Increased pressure from consumers on food retailers such as McDonalds and KFC have promoted a shift to antibiotic-free animal food products (Baertlein et al., 2015) and major food producers such as Tyson Foods and Perdue Farms have declared they will stop using antibiotics in broiler chicken production.

The Antibiotics Smart Use (ASU) program in 2007 offers an example of a successful awareness raising campaign in Thailand. ASU focuses on behaviour change among human health care providers through a campaign that promotes the rational use of antibiotics by strengthening human resources, improving health facility infrastructure and empowering communities. The project originally targeted three conditions that do not require antibiotic treatment: upper respiratory infections, acute diarrhoea, and basic wounds; conditions commonly treated with antibiotics. ASU has been cited as a best practice example of a behaviour change campaign with a focus on addressing antibiotic use at the community level and is included as a component of Thailand's policy actions to reduce AMU, including their Antimicrobial Resistance Containment Program (2012-2016).

Denmark offers an example of another behaviour change campaign with their Yellow Card system[4]. The system helps raise awareness about antimicrobial overuse by giving veterinarians a Yellow Card if they use antimicrobials in a quantity two times higher than the national average. Veterinarians are notified and encouraged to reduce usage. The system has been associated with an overall reduction of 22 percent in antibiotics use in pigs for the periods 2009-2015 (Ministry of Environment and Food of Denmark. 2016).

[4] Government Order No. 179 of February 26th 2014 on special provisions for the reduction of the consumption of antibiotics in pig holdings

Examples under Policy Domain 2: Evidence

AMR policy documents call for building the evidence base on AMR and AMU. European Union (EU) member countries provide several examples of recent action at a national and regional level. As an example of legislative action, to promote harmonized monitoring of AMR in zoonotic and commensal bacteria in the food chain, the EU passed Decision 2013/652/EU. In this Decision, the European Commission identifies the European Medicines Agency (EMA) as the lead agency in the collection of data on sales of veterinary antimicrobial agents in the member states. To ensure an integrated approach, the Decision stipulates that the EMA consult with stakeholders including the ECDC, EFSA and the European Community Reference Laboratory for Antimicrobial Resistance (EURL-AMR). The new legislation ensures harmonized monitoring systems in Europe, fosters comparability between the member states and between the human and veterinary sectors, and facilitates the monitoring of patterns of multi-drug resistance. In addition, the European Surveillance of Veterinary Antimicrobial Consumption project collects information on how antimicrobial medicines are consumed in animals across the EU.

Individual EU member countries provide examples of effective policy implementation to monitor AMU. In 2005, Denmark established the Danish Integrated Antimicrobial Resistance Monitoring and Research Programme (DANMAP). This program reports on usage and on the occurrence of antimicrobial resistance in zoonotic, indicator and pathogenic bacteria from animals, food and humans.

In the Netherlands, the independent Veterinary Medicines Authority (SDa) was established in 2010 to collect data on antimicrobial consumption on farms, establish benchmark indicators for individual major livestock sectors and analyze trends in consumption. The SDa is a public-private partnership between government and stakeholders from the major livestock sectors (pigs, broilers, veal calves and dairy cattle) and the Royal Dutch Veterinary Association (KNMvD). The SDa has three objectives: i. collect and report antimicrobial use data from farms and veterinarians; ii. establish annual targets for antimicrobial use in each livestock sector; and iii. develop species-specific benchmarks that differentiate between moderate, high, and very high users (farmers) and prescribers (veterinarians). Netherlands has the ability to continually improve the system based on a consistent stream of accurate data. Veterinarians enter prescription information in a Practice Management System and this is transferred to a central database. The information includes veterinarian and farm details, quantity supplied and animal species treated. Data are then transferred to databases held by private livestock quality assurance systems (Bos et al., 2013).

Japan and the United States of America provide additional examples of joint surveillance activities between sectors. In Japan, the National Veterinary Assay Laboratory (NVAL) oversees the technical aspect and the management of the Japanese Veterinary Antimicrobial Resistance Monitoring (JVARM) established in 1999. JVARM monitors the occurrence of AMR bacteria in food producing animals and the consumption of antimicrobials. Every year the AMR and AMU monitoring data are published. NVAL serves as the contact point with the human monitoring system called Japan Nosocomial Infectious Surveillance under the Ministry of Agriculture, Forestry and Fisheries. NVAL's research activities play a significant role in decision-making on risk management measures. For instance, in the early 2000s, Japan detected a rise in the percent of E. coli resistant to cephalosporins. It was speculated that the off-label use of ceftiofur simultaneously with the vaccination of eggs to prevent bacterial infection was contributing to the increase in E. coli resistance. Based on this finding, off-label use was voluntarily discontinued in 2012 and the percentage of resistance dropped substantially.

Japan uses data collected from the JVARM to conduct risk assessments to determine animal feed additives. Japan is currently implementing the following risk management measures to control what substances are added to animal feed: i. substances which pose a risk to human health are not designated as antibiotic feed additives; ii. specifying applicable animal species and breeding stages (products for lactation period, for fattening period, etc.); and iii. standard amounts to be added in feed. In addition, Japan conducts an annual national survey under JVARM to identify trends in AMR and to evaluate the effectiveness of each risk management measure. Risk assessments by the Food Safety Commission have yet to be conducted for certain antibiotic feed additives but this has been completed for additives which account for the majority of the total antibiotic feed additives in use. The extent of risks to human health of most ingredients have been designated as either 'negligible' or 'clearly absent' and therefore unnecessary for the risk assessment.

Japan's approach is based on the principles of risk analysis established by international standards. It considers the impacts of risk assessments on antimicrobial resistant bacteria on human health through food. The Food Safety Commission of Japan, the Ministry of Agriculture, Forestry and Fisheries formulate and implement risk management measures in accordance with the extent of the risks, taking into account the on-farm feasibility of such measures.

In the United States of America, the National Antimicrobial Resistance Monitoring System for Enteric Bacteria (NARMS) was established in 1996. NARMS is a collaboration among state and local public health departments, CDC, the United States of America Food and Drug Administration (FDA), and the United States Department of Agriculture (USDA). This national public health surveillance system tracks changes in the antimicrobial susceptibility of certain intestinal bacteria found in sick people (CDC), retail meats (FDA), and food animals (USDA). The NARMS program at CDC helps protect public health by providing information

about emerging bacterial resistance, how resistance is spread, and how resistant infections differ from susceptible infections.

In 2008, Congress required drug producers to report to the FDA on sales and distribution of antimicrobials for use in food-producing animals. Congress also directed the FDA to issue a summary public report that protects companies' proprietary information. From 2009 through 2013, the reports were just a few pages long with one table listing the total volume of drugs in use by antimicrobial class. Over time, the report has grown in length with the 2014 report providing more information on quantities of antibacterial classes labelled for administration to food animals. However, the reports do not yet provide information on exactly how the products are being used on-farm, such as the total amount of antimicrobials used for production efficiency, disease prevention, or control or treatment within each animal species.

Examples under Policy Domain 3: Practices

The Netherlands presents a best practice example for improving national response through a multi-faceted approach to AMR reduction. Instead of a high-level, centrally-controlled set of legal mandates, the Dutch implemented a system that combines legal mandates, widespread business practices and voluntary actions. The Taskforce on Antibiotic Resistance in Animal Husbandry was established to develop industry-specific action plans on AMR and a memorandum of understanding between stakeholders. The Taskforce includes representatives from every component of the food-animal value chain as well as government officials. The action plans include vigorous monitoring of antimicrobial use at the herd level, monitoring AMR and a clear designation of responsibilities for antibiotic use. The legal obligations and practices discussed below were developed and are implemented by public-private partnerships. The system's foundation is evidence-based practical legislation and its success is due to effective enforcement and clear designation of power and authority.

Farmers have several legal obligations to address AMR. They may procure veterinary services and medicines from only one veterinary practice. This reduces competition between veterinary practices and ensures the veterinarian knows the farm. Farmers must develop and implement Farm Health Plans (FHP) and Farm Treatment Plans (FTP). Both plans should be collaborations between the farmer and the farm veterinarian. The FHP must review farm-specific risk factors regarding infectious diseases. It must also detail specific management measures to control these risk factors and improve animal health. The FTP is a farm-specific

treatment protocol for the most common infectious diseases. Farmers must also register all prescribed and delivered antimicrobials5 (Beemer et al., 2010).

There are numerous examples of countries implementing bans on antimicrobials in animal feed. Republic of Korea provides a unique example as they were the first Asian country to implement a ban on antibiotics as growth promoters in animal feed in 2011. The Ministry of Agriculture, Food and Rural Affairs (MAFRA) implemented the ban to preserve the effectiveness of some antibiotics used to treat infections in humans. Before this ban, Republic of Korea gradually increased regulation on the use of antibiotics in animals by banning 44 types of antibiotics from being mixed into animal feed (MAFRA, 2011). These bans were driven by consumer demands, international action, and by scientific findings indicating side effects from livestock receiving too many antibiotics. The new rules will enhance the safety of local meat and dairy products. Under Republic of Korea's revised rules, eight types of antibiotics and one antimicrobial agent will be prohibited. Republic of Korea will permit veterinarians to treat sick animals with antibiotics.

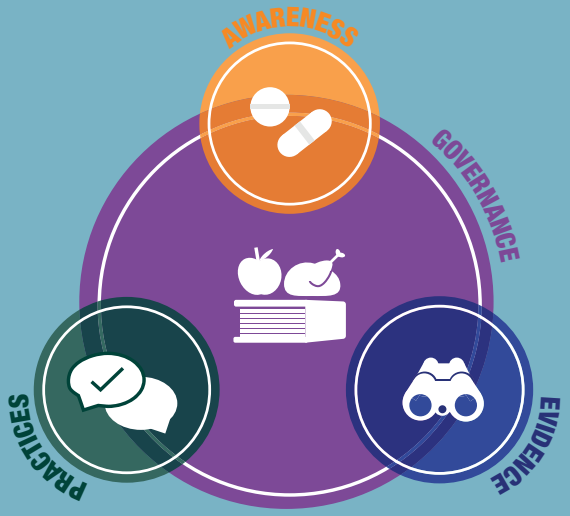
Examples under Policy Domain 4: Governance

response is a governance mechanism that takes a One Health, multi-stakeholder approach and involves non-governmental resources. The United States of America provides an example of formal stepwise action to define a governance mechanism on AMR. The National Security Council, in collaboration with the Office of Science and Technology Policy, coordinated with multiple agencies to develop a strategy in 2014. The President's Council of Advisors on Science and Technology provided recommendations published in a Report to the President on Combating Antibiotic Resistance in September 2014 (PCAST, 2014). Subsequently, an interagency Task Force for Combating Antibiotic Resistant Bacteria co-chaired by the secretaries of Health and Human Services, Defense, and Agriculture was given responsibility for developing a 5-Year National Action Plan issued in 2015.

Internationally, the United States of America demonstrated formal coordination on AMR through the Transatlantic Task Force Against AMR (TATFAR) together with the European Union in 2009 and by initiating the Global Health Security Agenda (GHSA) in 2014. The GHSA will also include international cooperation on AMR. The creation of the Presidential

[5] Animals Act (Ministry of Agriculture, Nature and Food Quality), Ormel amendment, Lower House of Parliament, 2009–2010, 31 389, no. 81.

Advisory Council on Combating Antibiotic Resistant Bacteria was created under a Presidential Executive Order by President Obama in 2014. This federal advisory committee was formed in 2015 to provide a formal mechanism for information sharing on national action plan progress by multiple agencies and to make recommendations to the Secretary of Health and Human Services who relays them to the President.


AWARENESS
GOVERNANCE
EVIDENCE
PRACTICES

SECTION 5:
POLICY RECOMMENDATIONS AND ACTIONS

Section 5 describes issues under four policy domains and potential policy actions with some suggestions for accompanying legislative actions that could be taken. The suggested actions are based on examples of regulatory responses to AMR from various countries and from AMR guidance documents. This Framework is non-prescriptive and recognizes there is no one-size-fits-all approach to addressing AMR that will work in all countries. The actions suggested in this section should be adapted to fit needs. Importantly, this Framework does not provide guidance for a legislative reform. All references to legislation are only for showing examples of how some policies could be implemented. For discussion on the legislative approach, the reader is referred to the FAO document on the "Methodology to analyse national legislation relevant for AMR".

Policy considerations for Domain 1: Awareness and education	
Concern/issue	**Policy recommendation**
Low awareness of AMR among the general public	Policy should be established or adapted to support participation in global, regional or national AMR awareness raising activities.
	Governments should designate authority to a specific ministry, department or office to coordinate and implement activities and initiatives to raise awareness on AMR among the general public.
	Policy should support ongoing efforts to raise awareness and inform the public about potential human and animal health risks from AMR.
	Governments can support awareness raising and education on AMR and AMU by ensuring resources are available to sustain ongoing efforts.
	Links between ministries and departments should be introduced or strengthened to ensure One Health coordination for AMR awareness raising.
	Language and terms to describe AMR should be aligned across sectors in awareness raising materials.

Policy considerations for Domain 1: Awareness and education	
Concern/issue	**Policy recommendation**
Low awareness of responsible antimicrobial use among veterinary students and veterinarians and other professionals	Policy should support the development and delivery of efforts to increase understanding, awareness and knowledge of what constitutes appropriate antimicrobial use among veterinary professionals. A consideration should be made on whether or not requirements for accrediting veterinarians for licensing renewal is dependent on knowledge of responsible antimicrobial use.
	Institutes of higher learning should integrate curriculum on AMR with other veterinary issues targeting graduate and undergraduate education for veterinarians and related professions.
	Governments should consider appropriate and feasible strategies for best reaching their audiences, for instance, including AMR policy in extracurricular activities for veterinary students.
Misuse and overuse of antimicrobials in food-animal production	Policy should support education and awareness raising initiatives that focus on promoting rational and responsible antimicrobial use for those involved in food-animal production.
	Specific antibiotic use behaviours and practices among workers in food-animal production may be highlighted and should include options to maintain health and prevent disease.
	Awareness raising on appropriate use of antimicrobials should encourage and support the use of alternatives such as probiotics to curb the need for antimicrobials in food animals. Published and globally endorsed production practices should be promoted.
	The government should engage with the private sector for awareness raising on AMR and promoting responsible use.
	Stewardship programs focused on antibiotic use in animals should focus on grouping antibiotics into three categories: human use only, animal and human use, and animal use only.
	Governments should adapt policy to educate and inform people about the responsibilities of regulatory authorities, legislation and drugs and antibiotics in relation to regulating antimicrobial use in animal food production.
	Efforts should be taken to increase awareness of existing legislation that regulates the use of antimicrobials targeting stakeholders in animal food production.

Policy considerations for Domain 2: Evidence	
Concern/issue	**Policy recommendation**
Limited reliable surveillance and monitoring data on AMR and AMU	National regulatory framework should clearly describe the development, implementation and maintenance of national surveillance and monitoring systems for AMR and AMU. Delegation of work and responsibilities should be clearly defined across sectors and by ministry, department or office.
	National legislation and procedures on AMR and AMU surveillance and monitoring should ensure consistency with existing mandates or legislation on reporting requirements.
	Harmonization should be made with regional or global surveillance systems on AMR and AMU including cross-border data sharing between countries.
	National policy related to surveillance and monitoring should describe a clear chain of command including designation of an appropriate authority and the establishment of legal mechanisms to ensure access to sample collection and processing.
	National policy should mandate allocation of ongoing resource appropriation for implementing AMR and AMU surveillance and monitoring systems. Support for surveillance should be ongoing to ensure sustainability and ongoing data collection.
	Coordination mechanisms between ministries and other agencies should ensure sharing of surveillance findings in a timely and efficient manner. Mechanisms may include legal coordination including signing a memorandum of understanding between ministries or agencies.
	Governments should identify and designate appropriate statutory and regulatory authorities at regional, provincial and district levels to be responsible for reporting on AMR surveillance.
	Governments should examine existing national legislation related to AMR surveillance to ensure animal health ministries, departments and agencies have the authority and capability to respond appropriately to emerging disease and public health emergencies related to AMR.
	Policy should describe regular dissemination of surveillance and monitoring data to policy-makers (including risk assessment findings) to inform national actions on AMR and mechanisms are established for sharing.

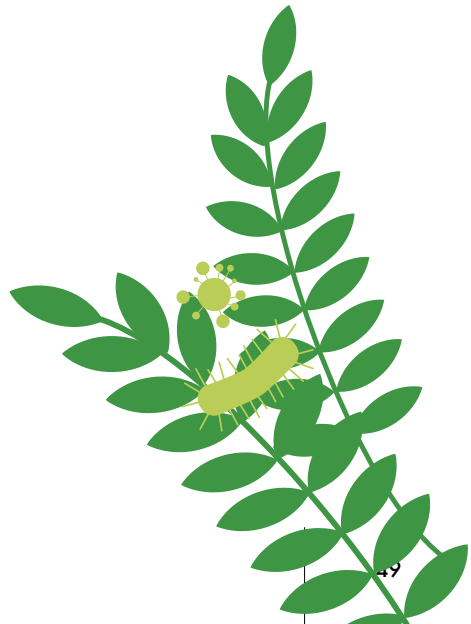
Policy considerations for Domain 2: Evidence	
Concern/issue	**Policy recommendation**
Limited reliable surveillance and monitoring data on AMR and AMU	Findings from AMR and AMU surveillance and monitoring systems should be translated into policy recommendations to inform future actions.
	Legislation should include residue testing in animal food products for domestic consumption and for export.
	Governments can establish mandates that require pharmaceutical and import companies to report annual antimicrobial sales.
	Policy should be established to support monitoring drug quality to reduce the use and distribution of counterfeit and substandard drugs.
	Governments can support laboratories for surveillance and monitoring activities through regular allocation of resources and by ensuring access to appropriate, state-of-the-art laboratory tests and reagents for the detection and identification of AMR pathogens.
	Legislation should describe official assignment of responsibility and authority to access laboratory findings.
Gaps in research on the use and distribution of antimicrobials and on antimicrobial resistance	Governments can delegate research, which is not part of ongoing AMR surveillance, to appropriate agencies, departments or institutions. This policy should be consistent with existing policies designating research in related areas.
	Policy should include guidance on the availability of scientific data to support the development of evidence-based and cost-effective policies.

Policy considerations for Domain 3: Practices	
Issue	**Policy action**
Limited or weak infection prevention and control standards and practices	Governments should establish policy to support and encourage good hygiene and farm management practices to ensure animal health.
	Policy should target critical control points for the spread of antibiotic resistance infection and support other measures to reduce infections in animals and the health impacts of inappropriate use by targeting veterinarians, farmers and others responsible for animal health.
	Governments should ensure farmers have access to the most effective treatment strategies in intensive animal production facilities.
	Policy should define training requirements on infection prevention and control and good animal husbandry practices for the animal health workforce, farmers and others involved in animal production.
	Legislation should be established to enact biosecurity standards and require compliance for farms.
	Animal disease control strategies should be enhanced as they relate to AMR. For instance, if an animal or group of animals suffer from recurrent infections requiring antimicrobial treatment, efforts should be made to eradicate strains of those microorganisms by determining why the disease is recurring and altering the production conditions and animal husbandry or management practices. The regulatory framework should clearly stipulate the responsible agency for implementing this action.
Discharges into the environment from antimicrobial use and production	The regulatory framework should reduce the environmental impact from industrial and agricultural sewage and runoff by implementing legislation to limit emissions of specific substances that may cause harm to human and animal health and the environment.
	Environmental regulators monitor and control pathways responsible for the release of resistance-driving substances into the environment (e.g. antimicrobials, metals, and biocides) and should play an important role in developing national policies to address AMR and AMU.

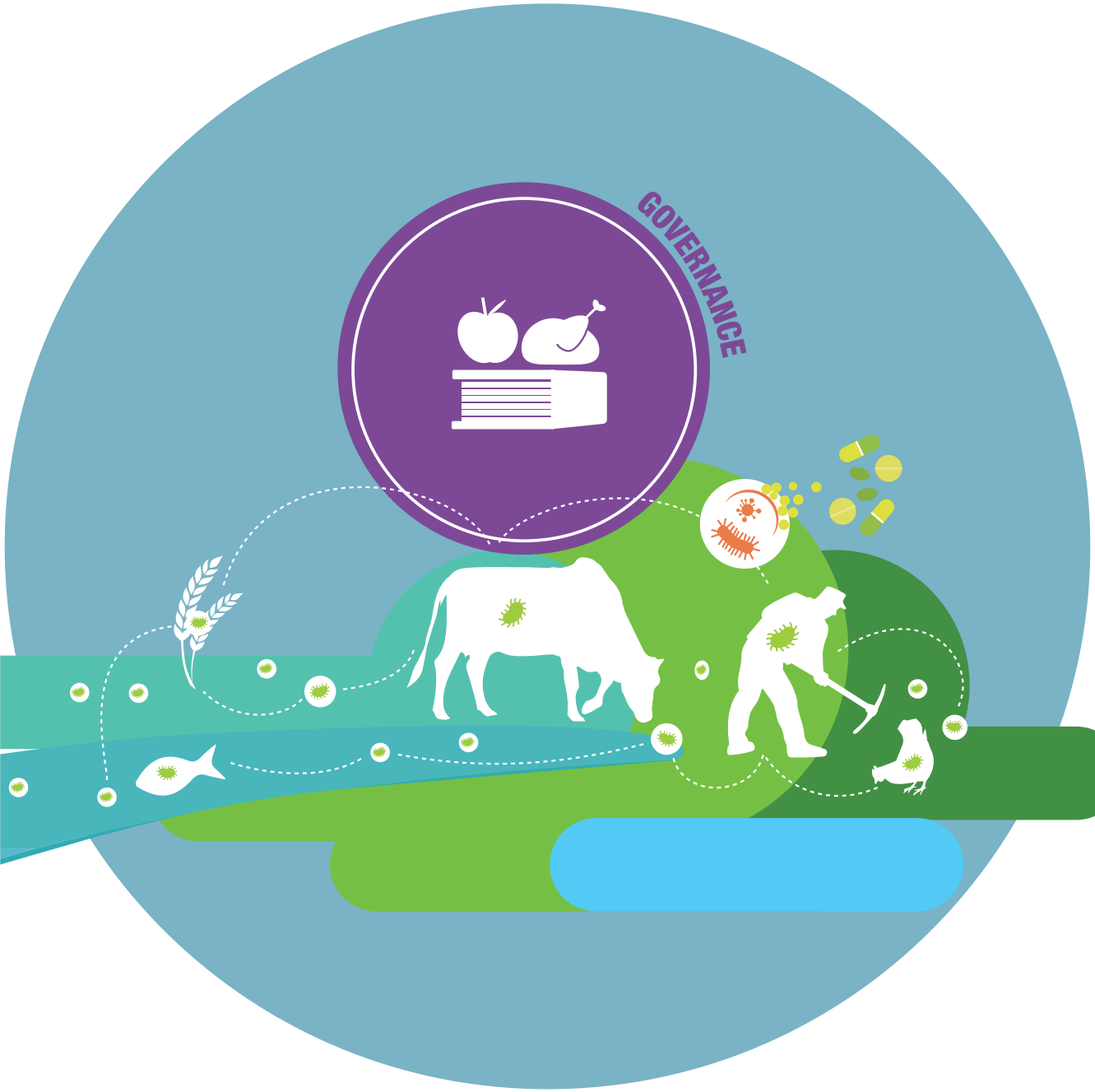
Policy considerations for Domain 3: Practices	
Issue	**Policy action**
Discharges into the environment from antimicrobial use and production	National governments and regulators should establish evidence-based, enforceable targets for maximum levels of antimicrobial active pharmaceutical ingredient discharge associated with the manufacture of pharmaceutical products.
	Legislation to monitor AMR should be established with a focus on antibiotic detection testing and environmental impact assessments.
Insufficient or non-existent standards for labelling and advertising antimicrobials for animals and agriculture	Legislation should be established to prohibit advertising that encourages non-prudent use of antimicrobial products.
	Governments should adopt legislation that limits advertising of prescription antimicrobials to veterinary professionals and not to the general public.
	Legislation should provide guidance on standards for labelling requirements. Labels on antimicrobials should be written in the national language, specify if the drug is for animal use only and state they should not be used after an expiry date.
	Legislation should allow authorities to ensure that advertising of veterinary antimicrobial drugs complies with the marketing authorization granted, in particular with the content of the summary of product characteristics and that it complies with national legislation.
Veterinary practices that contribute to the overuse or misuse of antimicrobials	Countries should develop veterinary guidelines (or prudent use guidelines) for prescribing and oversight of antimicrobials by veterinarians.
	Countries should consider legislation that requires veterinarians to prescribe only to animals under their direct care in accordance with legislation. The use of antimicrobials must be justified by a veterinary diagnosis in accordance with the current status of scientific knowledge.
	Legislation should be established that requires stakeholders such as veterinarians, pharmacists, drug retailers and farmers to record the sales and use of antimicrobials in food animals. The legislation should clearly define what information is required and to whom this information should be reported, who has access to this information (confidentiality to be maintained) and what authority will interpret and disseminate this information. An unbiased third party should collect and analyze this data.

Policy considerations for Domain 3: Practices	
Issue	**Policy action**
Veterinary practices that contribute to the overuse or misuse of antimicrobials	Governments should develop mechanisms to remunerate veterinarians and prescribers while limiting their ability to profit from antimicrobial sales and reorienting their roles away from commercial gains.
Rational and prudent use of antimicrobials	Develop and regularly review prudent use guidelines that include locally derived, species-specific treatment options.
	Expand development of prudent use guidelines to include all antibiotic uses and modify as new evidence becomes available.
	Clear guidelines on what types of antimicrobials can be used in food producing animals should be established and made available to all stakeholders.
	Clear and unambiguous definitions of prophylaxis, metaphylaxis and therapeutic uses should be established in legislation on the use of antimicrobials.
	Governments should ensure access to quality antibiotics for treatment of disease in animals.
	Bans should be made for use of antibiotics of highest priority and critical importance to people, based on international guidance from OIE and WHO.
	Actions including legal prohibitions should be established to phase out the use of medically important antimicrobials for production efficiency with consideration of local context and risk assessment.
	Guidance should clearly state if a prescription or other oversight is required for medicated feed and who is authorized to prescribe.
	Legislation should specify qualifications for mills to mix antibiotics into animal feed.
Illegal use and distribution of antimicrobials	Governments should approve and enforce legislation that bans importation, sale and use of antimicrobials not evaluated and registered by a veterinary pharmaceutical governing body. To support this legislation a clear delegation of duty or mission should be established with a specific agency to address the illegal distribution of antibiotics.

Policy considerations for Domain 3: Practices	
Issue	**Policy action**
Illegal use and distribution of antimicrobials	Distributors of antimicrobials should encourage compliance with national guidelines on the responsible use of veterinary antimicrobial drugs and should keep detailed records of all antimicrobials supplied according to the national legislation including: • date of supply • name of prescribing veterinarian • name of user • name of medicinal product • batch number • quantity supplied
	Legislation should clearly describe by whom and where antimicrobials can be sold and who may legally administer antimicrobials. Where appropriate, guidance should be provided on how antimicrobials can be sold through licensed or authorized distributions systems.
	Governments should ensure that the approval and implementation of quality standards is regulated in legislation for the production of antimicrobials and that quality control protocols are implemented and enforced.
Safe disposal of antimicrobials	Governments should provide guidance and requirements on safe disposal for unused and expired antimicrobials.



Policy considerations for Domain 4: Governance	
Concern/issue	**Policy action**
Limited governance in addressing AMR and AMU	A ministry, department or office should be given official delegation or authority to address AMR and AMU in animals and agriculture. Guidance on the scope of this mission should be specified including a description that clarifies their role in addressing AMR.
	Governments should ensure that agencies responsible for developing policies to address AMR and AMU in animals have clear and well-defined responsibilities.
	Governments should provide human and financial resources to government agencies to ensure development and enforcement of an adequate regulatory framework to address AMR and AMU.
	Systematic reviews of existing policies and a standardized system for policy examination should be applied and be open access.
A lack of governance mechanisms to address and coordinate AMR and AMU policy	National mechanisms should be established to manage and coordinate AMR policy across different levels of government and across sectors to ensure consistent and transparent application.
	Relationships should be formalized and strengthened between sectors in addressing AMR through mutual aid agreements, memorandums of understanding, inter-ministerial declarations and other appropriate mechanisms.
	Mechanisms should be enacted for AMR and AMU policy information sharing among sectors and stakeholders.


GOVERNANCE

SECTION 6:
STRENGTHENING AMR POLICY

Often, when addressing AMR, policy-makers feel pressure to make hurried decisions to meet the expectations of the public and international organizations. Impromptu policymaking can, however, result in decisions with unanticipated, even negative consequences for public health and adversely affect stakeholders. To avoid this, policy-makers should adopt rigorous, evidence-based approaches to policy making. Regular reviews of AMR and AMU policies determine if the national objectives are being achieved in a cost-effective way. The review process should consider changes in the nature of the problem, changes in the global and regional policy environment, and potentially unforeseen or unintended consequences of the available policy options. Policy reviews can determine whether a policy should be maintained, modified, or eliminated, whether implementation should be strengthened, whether an alternative policy action should be considered, and whether reassessment of the nature or source of a problem would be beneficial. After the review has been completed, the questions provided for each policy domain, and recommendations should indicate a course of action that addresses the policy gaps and strengthens existing policy. After stakeholders have a chance to inform the proposed course of action and consensus is reached, countries should ensure the proposed actions meet the needs of the national setting. The next three steps identify solution options for tailoring policy recommendations to fit a national context.

Adapting policy to fit the national context

With the increase in international pressure for countries to address AMR aligned to One Health, countries should make sure that interventions are appropriate and informed by the national context.

1. Establish multi-sectoral AMR working groups:

a. Establish working groups that include sectors beyond human and animal health such as environment, education and trade. The working group should include representatives from both the private and public sectors and recognized AMR experts. The working

group should coordinate and inform national action to address AMR. This group can also advocate for AMR action and build political support, establish local priorities and ensure that AMR is on the national political agenda.

2. Collect data

a. Collecting data on AMR is an important step to providing an accurate picture of national drug-resistant infection risks. Data can be used to establish local priorities and to provide benchmarks against which progress can be measured. It is also important to establish systems to collect data on antibiotic use in medicine and in agriculture. If countries lack the capacity to collect data, there may be opportunities for regional collaboration and data sharing and for the shared use of regional laboratory facilities.

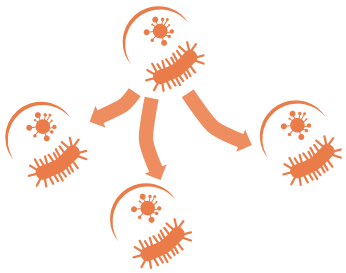
b. Implement uniform adoption of risk assessment methodologies at the national and international level to guide risk management actions.

3. Pilot projects

a. Pilot projects for proposed policies allow for cost-effective demonstrations in a local setting and generate guidance on how it could be adapted to a more specific context. Information on the practicalities of local implementation is particularly important. Implementation of AMR-related policies and programs should be accompanied by data collection for evaluation (see recommendations for collecting data at a national level in Section 5). Such information should be shared widely.

SECTION 7:
CONCLUSIONS

This Framework recognizes that policy and legislation provide a foundation for national action and response to AMR. However, there needs to be active engagement among stakeholders and strong political commitment among national leaders for effective response. Drawing on the understanding of AMR and AMU policy recommendations and reviewing national AMR policies, this Framework provides a guide for policy-makers in deciding when and how to intervene to address AMR and AMU through policy, but it does not provide comprehensive guidance for a legislative reform. For the latter, the reader is referred to FAO publication "Methodology to analyze AMR-relevant legislation in the food and agriculture sector". Although countries vary in their infrastructure, human resources, expertise and financial resources, this Framework provides a platform for developing effective AMR policy for all countries.



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