

Quadripartite One Health Legislative Assessment Tool for Antimicrobial Resistance



Food and Agriculture
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for Animal Health



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Abbreviations and acronyms

AMR	Antimicrobial resistance
ANIMUSE	Animal antimicrobial use
API	Active pharmaceutical ingredient
ASP	Antimicrobial Stewardship Programme
AWaRe	Access, Watch, Reserve classification
CAC	Codex Alimentarius Commission
CIA	Critically important antimicrobials
CPM	Commission on Phytosanitary Measures
CXA	Codex Glossary of terms and definitions
CXC	Codex Codes of Practice
CXG	Codex Guidelines
CXM	Codex texts on maximum residue limits
CXS	Codex Standards
EIA	Environmental impact assessment
EML	Model List of Essential Medicines
EMLc	Model List of Essential Medicines for children
FAO	Food and Agriculture Organization of the United Nations
FBO	Food business operator
FIP	International Pharmaceutical Federation
GBT	Global Benchmarking Tool
GLASS	Global Antimicrobial Resistance and Use Surveillance System
GMP	Good Manufacturing Practices
GXP	Good manufacturing, storage and distribution practices, including good cold chain management
IACG	<i>Ad hoc</i> Interagency Coordination Group on Antimicrobial Resistance
ICCPM	International Code of Conduct on Pesticide Management
IPC	Infection prevention and control
IPPC	International Plant Protection Convention
ISPM	International Standards for Phytosanitary Measures
MIA	Medically important antimicrobials
MRL	Maximum residue limit
NAP	National Action Plan

NPPO	National Plant Protection Organization
NRA	National regulatory authority
OHHLEP	One Health High-Level Expert Panel
OHLAT-AMR	<i>Quadripartite One Health Legislative Assessment Tool for Antimicrobial Resistance</i> (also referred to as “the Tool”)
OTC	Over-the-counter
PAHO	Pan American Health Organization
PSUR	Periodic Safety Update Report
PVS	Performance of Veterinary Services
R&D	Research and development
RMR	Risk management recommendation
SPS	Sanitary and Phytosanitary Measures
UNEP	United Nations Environment Programme
VLSP	Veterinary Legislation Support Programme
VMP	Veterinary medicinal product
VPP	Veterinary paraprofessional
WHO	World Health Organization
WOAH	World Organisation for Animal Health
WTO	World Trade Organization

Introduction



Introduction

1. Background

What is antimicrobial resistance and why is it a global challenge?

Antimicrobial resistance (AMR) occurs when microorganisms such as bacteria, viruses, fungi and parasites no longer respond to antimicrobial treatments. As a result of drug resistance, antibiotics and other antimicrobial agents become ineffective and infections become difficult or impossible to treat, increasing the risk of disease spread, severe illness and death.

There is strong evidence that antimicrobials are increasingly failing to cure infections and the research and development pipeline of novel antimicrobials is lacking. Therefore, AMR poses a significant threat to human, animal and plant health, food security, economic development and the environment by reducing the ability to respond to common infectious agents. In 2019, WHO declared AMR as one of the top 10 global public health threats facing humanity.

The Quadripartite framework and the “One Health” approach

The Food and Agriculture Organization of the United Nations (FAO), the United Nations Environment Programme (UNEP), the World Health Organization (WHO) and the World Organisation for Animal Health (WOAH) – collectively referred to as “the Quadripartite” – lead multisector engagement on AMR. The Quadripartite endorsed the definition of “One Health” provided by the One Health High-Level Expert Panel (OHHLEP), which reads:

One Health is an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems. It recognizes the health of humans, domestic and wild animals, plants, and the wider environment (including ecosystems) are closely linked and inter-dependent. The approach mobilizes multiple sectors, disciplines and communities at varying levels of society to work together to foster well-being and tackle threats to health and ecosystems, while addressing the collective need for clean water, energy and air, safe and nutritious food, taking action on climate change, and contributing to sustainable development (OHHLEP, 2022).

Thus the One Health approach integrates multiple disciplines that work locally, nationally and globally, recognizing that efforts in one sector alone, or single isolated interventions, cannot effectively address multisectoral challenges in the human-animal-environment interface – such as AMR. Risks and challenges exist across cross-sectoral, geographical and ecological boundaries, making this issue relevant for both developed and developing countries. The One Health approach should underpin the design and implementation of policies and legislation, and involves coordinated, collaborative, multidisciplinary and cross-sectoral frameworks and mechanisms. Applying a One Health approach to AMR means that policy, legal and institutional frameworks relevant to AMR should be holistic, integrative and coherent across human health, food safety, animal health and production, plant health and production, and the environment.

Accordingly, the *One Health Legislative Assessment Tool for Antimicrobial Resistance* (referred to as “the OHLAT-AMR” or “the Tool”) integrates the One Health approach in assessing legal frameworks to address AMR via two pathways. First, it examines the role of legislation for multi-stakeholder governance mechanisms in AMR management, as well as other multisectoral responses that would benefit from legal underpinning. Second, the Tool has incorporated a One Health approach in each sector through specific provisions in legislation that equip each regulatory area with the requisite legal tools for consistent action across the various disciplines.

Legislation to prevent and address AMR risks and challenges

Legislation delineates the roles and responsibilities of government and other stakeholders and makes them accountable. Legislation enshrines mechanisms for coordination, establishes regulatory mechanisms for control (e.g. permits and inspections) and enables enforcement (e.g. through sanctions). Legislation can also be a powerful tool to frame effective public-private collaboration, including through frameworks of co-regulation. In identifying norms needed to strengthen national legal frameworks, it is essential that the analysis is undertaken in a holistic manner that pays attention to multiple sectors and legal instruments, to identify gaps that might well be overlooked in any single sector. Each of the sectors relevant to AMR responses, set out in the chapters that follow, are typically governed by separate legal instruments that are often drafted with little consideration of the synergies and implications across the sectors. The subsequent chapters show that many regulatory areas are required to address the spectrum of AMR risks comprehensively. Furthermore, national laws may not be well aligned with relevant international standards.

In line with the One Health approach, it is important to recognize and integrate gender perspectives when addressing AMR, in particular given the different impacts and roles between genders in health, agriculture, and environmental sectors. In particular, because gender inequalities shape access to information, health care, financial resources and paid employment, these inequalities can shape AMR risk and vulnerability. Accordingly, AMR legislation can be a valuable tool for reducing these inequalities, in particular through gender neutral language and sharing and reporting requirements.

2. Objectives of the One Health Legislative Assessment Tool for AMR

This *One Health Legislative Assessment Tool for AMR* provides guidance on how to assess national legislation relevant to addressing AMR. The Tool assists in identifying regulatory gaps in the legislative framework and enables prioritization of potential solutions.

FIGURE 1. Chapters of the *Quadripartite One Health Legislative Assessment Tool for AMR*



Each chapter (see Figure 1) represents a sector which can potentially contribute to the development and spread of AMR and presents an overview of the relevant AMR issues, as well as outlining where they might be addressed in the legislative framework. Explanations are provided on which key elements pertain to the regulatory area or mechanism under review (guided by international standards). Thus, a simple distillation of the key principles and mechanisms that should feature in legislation is presented. This is followed by a set of simple questions to facilitate a finding of whether or not the national legislation contains the aforementioned features/mechanisms.

It should be noted that the Tool is comprehensive in terms of AMR but is not exhaustive of each regulatory area under review *per se*.

3. How to use the Tool

The process of using the Tool for the legal analysis

The Tool is created to apply to national or subnational settings, but can be applied to regional multilateral organisations as well. The Tool enables broad One Health assessments of AMR-relevant legislation by focusing, through core questions, on the key regulatory elements across all sectors. The Tool can therefore be applied as a whole to gain most benefit from One Health insights and synergies, but chapters can also be applied separately. The process of applying the Tool can be decided by national authorities and/or the national coordination group for AMR, but the following process in Figure 2 corresponds to the recommended steps to take.

How to apply the Tool as a national lawyer

The Tool is divided into chapters corresponding to sectors relevant to AMR. Each chapter is then divided into sections that address key regulatory themes/areas relating to AMR.

First an **Overview** is provided of what the key AMR risks and challenges are, and this part states how the regulatory theme is relevant to, or can be used to address, the AMR challenge. This is the section that outlines why the regulatory area is important. Next, the part entitled **Where is XX regulated** identifies the possible laws in which relevant information can be found. After this, a description of key features of legislation compliant with relevant international standards is set out in parts entitled **Key elements of XX provisions** or **Key elements for XX**. This part serves to provide comprehensive information needed to conduct the analysis (i.e. this part sets out what should be regulated and how, and facilitates answering the questions). The list of **Questions** in each section should be answered using the preceding part as the relevant benchmarks. Answers may be found across multiple instruments in the country's legal framework (guided by the **Where** part above). Some elements may be found in a primary law, others in secondary legislation or under a separate law entirely. **In responding to the questions, a citation of where the answer is derived from is required (e.g. Veterinary Drugs Act (2009), Article 42(3)).**

The Tool is self-standing and it is not necessary to use or access resources other than the information in the chapters in order to conduct the assessment. Nevertheless, links to international standards have been provided for ease of reference.

The focus of the Tool is the legislative framework rather than what occurs in practice. Thus, answers to the questions should cite appropriate legislative provisions to demonstrate findings and conclusions. It should be highlighted that **legislation does not need to refer directly to AMR (or antimicrobials, etc.) to be useful or relevant.** The information sought through the questions are legislative provisions that may provide a suitable basis for regulatory action. This may in some cases involve a minor amendment to existing legislation or, alternatively, provisions may be phrased broadly enough to accommodate the inclusion of AMR-specific or AMR-relevant considerations without an amendment. For this reason, it is possible that much of the legal framework may be usable as it is to respond to AMR challenges. However, it is also possible that there are gaps or major weaknesses in a regulatory area – these will be unique to each country.

During the course of the analysis, it is possible that inconsistency is discovered among different laws. This is more likely where countries have sectoral legislation that may be outdated or fragmented, with amendments made in a haphazard manner over time. Where relevant to the questions asked in the sections, **these inconsistencies should be highlighted.**

Further, it is also possible that the legislation may not reflect gender-neutral drafting trends, in particular in the English language (i.e. use of the pronoun “he” to refer to all genders). In addition, the legislation may contain considerations that are geared more toward certain genders than others (i.e. focus more on professions or roles traditionally filled by one gender). Gender-neutral language should therefore be considered and suggested during the review process in order to ensure that the legislation applies equally to all actors and stakeholders.

FIGURE 2. The process for using the *Quadripartite One Health Legislative Assessment Tool for AMR*



References for Introduction

One Health High-Level Expert Panel (OHHLEP), Adisasmito, W.B., Almuhairi, S., Behraves, C.B., Bilivogui, P., Bukachi, S.A., et al., 2022. One Health: A new definition for a sustainable and healthy future. PLoS Pathog 18(6): e1010537 (<https://doi.org/10.1371/journal.ppat.1010537>, accessed 10 July 2023).

Chapter 1

Institutional frameworks and cross-sectoral legislative responses to antimicrobial resistance



1.1 Institutional frameworks for AMR

One Health is a collaborative, multisectoral and multidisciplinary approach that recognizes the health of humans, domestic and wild animals, plants and the wider environment (including ecosystems) are closely linked and interdependent (OHHLEP, 2022). The FAO-UNEP-WHO-WOAH Quadripartite collaboration on AMR and the *One Health Legislative Assessment Tool for AMR* are grounded in advancing the One Health approach.

A fundamental premise of applying the One Health approach to the governance of antimicrobial resistance (AMR) means that AMR management should involve all the different sectors and disciplines that are relevant for AMR, as well as all the entities with a relevant mandate at central and decentralized levels. The Global Action Plan for AMR and the report of the *Ad hoc* Interagency Coordination Group on Antimicrobial Resistance (ICG) recommend countries to set up an AMR multisectoral governance arrangement. Depending on its structure and functions, a governance arrangement may require legal underpinning in order to operate. In countries where this is not essential, legislation can contribute to facilitate multisectoral coordination by providing a framework of accountability and making such arrangements sustainable in time.

As AMR has multiple drivers and must be tackled on many fronts, this chapter explores governance arrangements through the institutional frameworks and processes, as well as cross-sectoral legislative responses that implement multidisciplinary solutions to AMR.

Where can institutional frameworks be found?

This chapter examines legal instruments enacted to establish an AMR governance structure at the national level. Such instruments might be specifically established to address AMR governance. Alternatively, the legal instrument may pertain more broadly to public health, One Health, emergency preparedness or other related cross-sectoral themes.

National Action Plans (NAPs) may describe governance arrangements for AMR in various countries and may require legislation to give such arrangements legal force and authority. This chapter focuses on institutional frameworks as set out in legislation.

Key elements of institutional frameworks

AMR governance should comprise a multisectoral coordinating group with the representation of appropriate ministries and authorities – including those responsible for human health, food safety, agriculture/animal health and production/plant health, and the environment. These bodies may involve representatives from the subnational level. Legislation serves to establish institutional structures with the force and authority of law and should align legally established mandates across the legislative framework.

Legislation should at a minimum establish: 1) the composition of such a body; 2) a clear scope of functions for such a body; 3) an identification of the authority to whom such a body is accountable (i.e. a specific ministry, the Council of Ministers, etc.); 4) the roles and responsibilities of members; 5) the mechanisms for reporting and information exchange among constituents, and 6) mechanisms for monitoring.

The functions of such a body may differ according to the needs of countries and may include, *inter alia*: coordination and cooperation; development and oversight of implementation of AMR policies and programmes; development of the knowledge base for policies and guidelines; establishment of an integrated surveillance system for AMR; development and implementation of programmes (e.g. education-based Antimicrobial Stewardship Programmes [ASPs]), research and development (R&D); mobilization of resources, budget allocation, management and investment; and facilitation of public-private partnerships.

Such coordinating bodies may or may not include private stakeholders directly in decision-making or composition. If private entities are included as members of the body, and the body includes executive or regulatory functions, it is important to ensure that there are mechanisms in place to prevent potential conflicts of interest.

Questions on institutional frameworks

1. Is there a National Action Plan for AMR?
 - a. Does the NAP establish/refer to a multisectoral body for AMR coordination?
2. Is there a coordination mechanism for AMR?
 - a. Is this approved by legislation?
 - b. Does this body include at least the representatives from human health, animal health/production (terrestrial and aquatic), plant production and the environment?
 - c. Are the composition, mandate and decision-making powers of the AMR coordination mechanism defined? If yes, please describe.
 - d. Is there participation of the private sector?
 - e. Does this body have mechanisms/provisions to facilitate coordination:
 - i. across ministries;
 - ii. between the central and the decentralized authorities;
 - iii. between public and private actors?
 - f. Is there a reference to its funding?

1.2 Cross-sectoral legislative responses to AMR

Where can relevant information be found?

This section looks at legislation that addresses AMR across multiple sectors. This may be found in *self-standing legislation* specific to AMR, or in *AMR-specific provisions* in broader legislation that addresses cross-cutting or multidisciplinary areas such as One Health, zoonoses or emergency response.

Key features of cross-sectoral provisions for AMR in legislation

Legislative interventions attempting cross-sectoral or multidisciplinary solutions for AMR should ensure policy coherence across AMR-relevant sectors. AMR-specific responses in legislation may be based on any area identified in the AMR policy or NAP, including: antimicrobial use and AMR stewardship; structural financing of AMR responses; integrated surveillance programmes, and initiatives to improve effective AMR communication and awareness.

Some countries have enacted AMR-specific legal instruments – i.e. single laws or regulations that address technical aspects of regulation found in other chapters of this Tool. While the purpose, scope and principles of these legal texts

are too varied and context-specific to describe here, several points of caution are highlighted. With the exception of legal instruments addressing the institutional framework or setting out cross-sectoral responses, AMR-specific legislation that seeks to fill regulatory gaps in the various sectors runs the risk of legal fragmentation or duplication.

Questions on cross-sectoral responses to AMR in legislation

1. Other than the institutional frameworks, are other elements included in AMR multisectoral legislation? (Please describe)
2. Does this result in fragmentation of any other regulatory areas?

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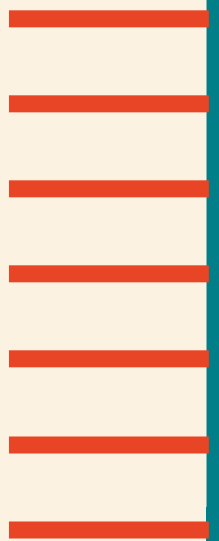
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Chapter 2

Human health



2.1 Antimicrobials and human health

Overview

Antimicrobials treat both simple and severe infections and facilitate common medical procedures such as surgeries and cancer care, forming the backbone of modern medicine. AMR makes microorganisms resistant to antimicrobials, making them less effective when used for the prevention or treatment of infections during these common procedures (WHO, 2021).

Key regional documents on AMR legislation for human health

Pan American Health Organization (PAHO). [Legislación sobre antibióticos en América Latina](#) (Antibiotic legislation in Latin America) (Spanish only) (2004).

Pan American Health Organization (PAHO). [Recommendations for implementing antimicrobial stewardship programs in Latin America and the Caribbean: manual for public health decision-makers](#). Chapter II.7 Ethical and Legal Considerations, and Economic Issues (2018).

WHO Regional Committee for Africa Resolution AFR/RC66/R2. [Regional strategy on regulation of medical products in the African Region, 2016–2025](#) (also in French, Portuguese) (2016). The Regional Committee also adopted the African Union Model Law on Medical Products Regulation (also in Arabic, French, Portuguese).

WHO Regional Office for the Western Pacific. [Better laws for better health: Western Pacific regional action agenda on strengthening legal frameworks for health in the Sustainable Development Goals](#) (2020).

2.2 General institutional framework for human health relevant to AMR

Overview

The rise of AMR presents challenges for national health-care systems at the levels of government and health-care institutions and professionals. The general institutional framework for human health and the specific arrangements for AMR are important for setting out the roles and responsibilities of various entities in the national health-care system.

Where are AMR institutional frameworks in the human health sector regulated?

General approaches to AMR institutional framework in the human health sector may be found in primary legislation relevant to public health and health care. The latter includes laws on health (including public health and health care at

both central and decentralized levels), health promotion, and the prevention and treatment of infectious disease (also called communicable disease/infection control legislation). Specific institutional arrangements for AMR governance in the health sector are also detailed in NAPs for AMR (see also in this Tool, Chapter 1).

Key elements for a human health institutional framework

Institutional arrangements for AMR specific to human health

Institutional arrangements can be addressed in NAPs for AMR, which, according to the Global Action Plan on AMR, should set out national and local governance arrangements (WHO, 2015). NAPs may establish specific institutional arrangements for the human health sector.

General institutional framework

Public health is often at least partially decentralized. For AMR, this poses challenges of coordination and uniform policy-making and implementation. A focal point for AMR should be established by the Ministry of Health.

Legislation should establish a coordination mechanism at the ministry responsible for public health. Formalized coordination through legislation can facilitate communication on AMR, as well as facilitating financing, donor funding applications, reception and exchange of data relevant to AMR, and the coordination of common projects, as well as other aspects of AMR mitigation and prevention. Legislation can determine the composition of the mechanism, which may benefit from the inclusion and representation of all key stakeholders within the public health domain, including both centralized and decentralized authorities, as well as public and private health-care providers (WHO, 2021).

Questions on the human health institutional framework

The National Action Plan and focal point

1. Is there a National Action Plan for AMR?
 - a. Does the NAP set out specific institutional or governance arrangements for human health? If yes, are these arrangements also found in legislation?
2. Is a health ministry focal point for AMR identified either by law or in practice?

General institutional framework

3. Does the public health or infectious diseases legislative framework provide for coordination among authorities:
 - a. with a role in human health, including decentralized authorities (if so, please state the type of, and mechanism for, coordination);
 - b. with a role in addressing AMR in sectors other than human health (if so, please state the sectors and the type of coordination)?
4. If health-care delivery is decentralized, are AMR focal points identified within the regional/provincial or local institutional frameworks?

Sources of international guidance for institutional frameworks for AMR in the human health sector

WHO. [Policy guidance on integrated antimicrobial stewardship activities](#) Chapter 5.1 Establish a national coordination mechanism for AMR (2021).

WHO. [Benchmarks for International Health Regulations \(IHR\) capacities](#) (2019).

WHO, FAO, WOA. [Sample terms of reference for a national multisectoral coordinating group, for a national focal point and for a technical working group](#) (2016).

2.3 Medicines and health products legislation in the human health sector for AMR

Overview

The regulation of human medicines and health products is fundamental to the management and containment of AMR in the human health sector. The WHO Global Benchmarking Tool (GBT) replaces previous tools used to evaluate national regulatory systems for medicines and health products and is designed to evaluate the overarching regulatory framework and the component regulatory functions. The present Tool focuses exclusively on legislation and medicines (not vaccines, blood products, diagnostics or medical devices). Accordingly, AMR-specific elements were added to the GBT, which also includes sections focusing on clinical trials oversight and national regulatory authority (NRA) lot release that are not included in this chapter.

Important additional tool: WHO Global Benchmarking Tool Revision VI for evaluation of national regulatory systems of medical products

Many countries have already gone through formal benchmarking with the WHO GBT. The national legal evaluation of the public health sector should build on the outcomes of these evaluations.

More information on the WHO GBT and translations (Revision VI) can be found here: <https://www.who.int/tools/global-benchmarking-tools/VI> (2021).

Where are antimicrobials as medicines regulated?

A public health law typically establishes the powers of the competent authorities over medicines and health products. In addition, a primary comprehensive medicines law that sets out the rules on overarching regulatory aspects of medicines is also common. Such laws have diverse titles (including, for example, *Medicines and Related Substances*; *Food and Drug (and cosmetics)*; *Pharmaceutical (Affairs)*; *Controlled Drugs and Substances*; *Pharmacy and Poisons*; *Drug Administration*). It is possible that, in some countries, animal medicines (e.g. veterinary medicinal products, as described in Chapter 4 of the Tool) are included in medicines laws. General laws on commerce and consumer protection are also applicable to medicine sales. Self-regulatory elements regarding manufacturing and other types of practices may also be set out by industries and professional bodies.

2.3.1 Institutional arrangements for regulating medicines

Key framework elements for institutional arrangements

A well-functioning national (medicines) regulatory authority is primarily responsible for the management and control of medicines. This can be the ministry responsible for health, one or more department(s) within this ministry, or possibly one or more entities that function outside of the ministry as independent institutions. The NRA is responsible for ensuring: access to antimicrobials; the quality, safety and efficacy of antimicrobials; appropriate and prudent use of antimicrobials, and compliance with regulations. Parts of the responsibilities for medicines control – such as pharmacovigilance and procurement – can be situated outside the NRA. In such cases, collaboration between these entities is required.

These government bodies or agencies may be found at different levels of the state (i.e. they may be decentralized). These mandates should not overlap, especially when there are complementary or shared responsibilities between bodies (GBT RS01.02). Administrative and other arrangements (such as the designation of coordinators or focal points) for communication and coordination should therefore be established (GBT RS01.02, RS01.03), in addition to mechanisms to facilitate the exchange of information (GBT RS01.03, RS02.01). In line with good governance approaches, the structure and line of authority among and within all institutions should be set out (RS02.01). Finally, guidelines for regulatory activities should also be developed and adopted to ensure consistency in application among bodies under the NRA (GBT RS01.04).

Questions on institutional arrangement

Governance of the NRA and core functions and powers (GBT RS01.02)

1. Does legislation identify an NRA? What is/are the lead agency or agencies?
2. As regards the NRA and other regulatory institutions for human medicines, does legislation establish:
 - a. functions/roles (responsibilities) and powers?
 - b. mechanisms for coordination among institutions where there is more than one (e.g. at central and decentralized levels)?

Source of international guidance: institutional frameworks

WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems of medical products. Revision VI, Section 01 – National regulatory system. (2021).

2.3.2 Medicine and antimicrobial definitions

Key elements of definitions

Legislation will define the key terms used in the law, such as human medicine (possibly termed drug or pharmaceutical). The definitions used will affect the scope of application of the law and possible leave gaps in regulation or overlaps where there has been inconsistency across the relevant legal framework (GBT RS01.01). In some cases, various human medical products with antimicrobial activity may fall under terms that are defined (or not) in legislation, such as “traditional medicine”, “alternative medicine”, “herbal medicine” or “supplements”.

Question on definitions

Definition (GBT RS01.01)

1. Can antimicrobials fall under other categories than medicines within the medicine legislation (e.g. traditional/alternative/herbal medicine or supplements)?

Source of international guidance: definitions

WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems of medical products. Revision VI, Section 01 – National regulatory system (2021).

2.3.3 Essential medicines and Access, Watch, Reserve classification

Overview

Ensuring that quality essential medicines and health products are available in sufficient quantities and are affordable to the population involves a complex interplay of regulatory and procurement systems, legal provisions for universal health coverage or other models of health coverage, and efficient management of resources.

Key elements of access to medicines

Essential Medicine Lists

The WHO Model List of Essential Medicines (EML) and the WHO Model List of Essential Medicines for children (EMLc)

provide core lists of essential medicines for priority conditions and can be used as a basis for developing or updating national formularies and national EMLs. The legislative framework may contain provisions to integrate the WHO Model Lists, or these lists may appear as annexes to primary or secondary legislation. Lists annexed to primary or secondary legislation should be periodically updated.

The WHO Access, Watch, Reserve classification (AWaRe)

The legislative framework may contain provisions to integrate the WHO AWaRe classification in order to evaluate and monitor the use of antimicrobials and to inform appropriate use practices (WHO, 2021). The AWaRe classification categorizes antibiotics into “Access”, “Watch” and “Reserve” categories to enable access to antibiotics while also facilitating their good stewardship. Although the AWaRe categorization can be used in legislation for target-setting, stewardship, medicine legislation or surveillance, such legislation is innovative and the AWaRe document generally guides policy.

The Access category contains antibiotics that are often first- or second-line treatments for priority infectious syndromes and have a lower potential for resistance. Accordingly, medicines in this group should be widely available and affordable. The Watch category contains antibiotics that are considered to be at higher risk for AMR but are still recommended second-line treatments for narrow indications. The Reserve category comprises antibiotics that should be kept as a last resort for the treatment of multidrug-resistant infections. WHO encourages a countrywide target of at least 60% of antibiotic consumption from medicines in the Access category.

Questions on access to medicines

1. Is there legislation that establishes a national essential medicines list?
2. Does legislation (or the national medicines policy) adopt the WHO AWaRe classification or a similar national system for antimicrobials in the national formulary, national EML, stewardship guidelines or treatment guidelines?

Sources of international guidance: access to medicines, WHO Model Lists and AWaRe

WHO. [WHO Model list of essential medicines – 22nd list \(2021\)](#).

WHO. [WHO Model list of essential medicines for children – 8th list \(2021\)](#).

WHO. [Access, watch, reserve, classification of antibiotics for evaluation and monitoring of use \(2021\)](#).

2.3.4 Marketing authorization and registration

Overview

Marketing authorization and registration refer to a procedure for approval of a medicine for marketing after it has undergone a process of evaluation. The evaluation ascertains the safety, effectiveness and quality of the medicine, in addition to validating the relevance of corresponding data linked to a suitable strategy for monitoring drug safety through pharmacovigilance.

Key elements of registration and marketing authorization

Legislation should state that a medicine can be imported, manufactured, distributed, sold or supplied to end-users only if it is registered. These provisions should be reinforced by penalties or sanctions in the event of non-compliance (GBT MA01.01).

Legislation should empower the NRA to conduct registration or marketing authorization and should empower the entities within the NRA that have the mandate for registration, including appropriate lines of reporting (GBT MA02.01).

Once the product is registered, such medicine should be included in a publicly available list of approved or registered medicines. An important aspect of the registration process is the classification of antimicrobials according to how they are dispensed or sold, the most important categories being prescription-only and over-the-counter (OTC). Such classification is often found in a medicine or drug schedule.

Legislation should state when and how the NRA may withhold, suspend, withdraw or cancel a marketing authorization due to quality, safety or efficacy concerns (GBT MA01.02). This includes if there is new information on the effects of the medicine, or if the requirements outlined in the registration are not met.

Owing to the risk of AMR for fixed-dose combinations, or a combination of two or more active pharmaceutical ingredients in a fixed ratio of doses of which at least one is an antimicrobial, legislation may specify requirements for registration of these combinations (WHO, 2005). WHO provides a list of antibiotics that are not recommended as part of the WHO AWaRe classification for these combinations (see WHO Adopt AWaRe: Handle antibiotics with care).

Questions on registration and marketing authorization

Core legal elements (MA01.01-01.02 + MA01.04)

1. Does legislation require registration before placing a medicine on the market, or for manufacture, import, sale or distribution?
2. Are there provisions requiring the NRA to withhold, suspend, withdraw or cancel a registration if there are issues with quality, safety and efficacy?

Fixed-dose combinations

3. Are there laws, standards or guidelines for the evaluation, development and approval of fixed-dose combination medicines?

Medicine scheduling

4. Do medicine schedules under legislation establish medicines that are categorized as prescription-only?
5. Are there other medicine schedule categories?
 - a. Is there a special category of medicines that are for hospital use only?

Sources of international guidance: registration and marketing authorization

[WHO Global Benchmarking Tool \(GBT\) for evaluation of national regulatory systems of medical products](#). Revision VI, Section 02 – Registration and marketing authorization (2021).

WHO. [Guidelines for registration of fixed-dose combination medicinal products](#). Annex 5, WHO. Technical Report Series, No. 929 (2005).

WHO. [Adopt AWaRe: handle antibiotics with care](#) (2023).

2.3.5 Licensing of establishments and regulatory inspections

Overview

Licensing is a regulatory mechanism which, coupled with inspections, ensures the quality, safety and efficacy of medicines (GBT 05). This regulatory mechanism allows the NRA control over various aspects and operations of a licensed establishment. Regulatory inspections ensure that operations at establishments that deal in medicines are carried out according to approved standards and legislation.

Key elements of licensing of establishments

Legislation should establish license-to-operate requirements for establishments, premises and facilities throughout the medicines supply chain. This includes facilities of manufacturers, distributors, wholesalers, importers, exporters and retailers (GBT LI01.01). The NRA should have the power to issue, suspend or revoke licenses (GBT 05), and legislation should establish decision-making criteria to support these decisions (GBT LI04.01). Legislation should require that a list of all licensed facilities is publicly available (GBT LI05.01).

Legislation may require the adoption or application of Good Practices by licensees – i.e. good manufacturing, storage and distribution practices, including good cold chain management, collectively referred to as GXP. An inspections system may be used to verify compliance with GXP as a condition to receive, maintain or renew a licence.

Legislation may establish a national quality laboratory to assess the quality of medicines during registration and market surveillance. Where certain laboratory resources are not available in the public sector, the NRA may delegate any testing to be carried out by private, foreign authorized or accredited laboratories. Inspection and testing schemes support the enforcement of rules regarding medicines (including antimicrobials). Inspections may also involve the inspection of self-audit records or quality assurance systems.

Questions on licensing

Core legal elements (LI01.01-LI01.05)

1. Does legislation require the licensing of establishments throughout the medicines supply chain?
2. Does legislation require the application of Good Practices by licence holders?
 - a. Is there a system of inspections to enforce these requirements and standards?
3. Does legislation empower the NRA to issue, suspend or revoke licences?

Core legal elements for regulatory inspection (RI01.01-RI01.05 + RI02.01)

4. Does legislation set out a framework for risk-based inspections at all phases of the medicines supply chain?

Core legal elements for laboratory testing (LT01.01-RI01.02 + LT02.01)

5. Does legislation establish a national quality control laboratory to perform testing for quality control?
6. Does legislation authorize the NRA to delegate the required testing services where needed?

Source of international guidance: licensing and regulatory inspections

WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems of medical products. Revision VI. Sections 05/06 – Licensing establishments/Regulatory inspection (2021).

2.3.6 Manufacturing

Overview

Good manufacturing practices for finished pharmaceutical products and active pharmaceutical ingredients are key to ensuring the quality of antimicrobials. Manufacturing of antimicrobials raises specific environmental concerns (see in this Tool, Chapter 7).

Key elements of manufacturing

In addition to licensing aspects (section 2.3.5), legal provisions for manufacturing may contain specific rules. Legislation should require manufacturers to keep records of their operations and the quantities produced. This can contribute to the collection of accurate data on the amount of antimicrobials entering the market.

Environmental pollution from the manufacturing of medicines and health products can be legislated through standards in the production process. The detailed requirements for waste and wastewater management during the production of antimicrobials are contained in WHO's *Good manufacturing practices for pharmaceutical products containing hazardous substances* (2010).

Questions on manufacturing

1. Does legislation require manufacturers to keep records of the antimicrobials or antimicrobial active pharmaceutical ingredient (API) they produce?
2. Does legislation on manufacturing include any environment-related obligations for production? Do these obligations include:
 - a. waste and wastewater management;
 - b. manufacturer liability for waste;
 - c. specific standards for antimicrobial waste in the manufacturing process (for active pharmaceutical ingredients and finished pharmaceutical products)?

Sources of international guidance: manufacturing

WHO. [Good manufacturing practices for pharmaceutical products: main principles](#). Annex 2, WHO Technical Report Series, No. 986 (2014).

WHO. [Points to consider for manufacturers and inspectors: environmental aspects of manufacturing for the prevention of antimicrobial resistance](#). Annex 6, WHO Technical Report Series, No. 1025 (2020).

WHO. [Good manufacturing practices for pharmaceutical products containing hazardous substances](#). Annex 3, WHO Technical Report Series, No. 957 (2010).

WHO [Global Benchmarking Tool \(GBT\) for evaluation of national regulatory systems of medical products](#). Revision VI, Section 05 – Licensing establishments (2021).

2.3.7 Market surveillance and control

Overview

By ensuring that medicines on the market conform to applicable laws, market surveillance facilitates consumer protection. Market surveillance and control legislation is therefore primarily concerned with four themes: 1) control of

imports; 2) prevention of, detection of and response to substandard and falsified medical products; 3) monitoring the quality of medicines throughout the supply chain; and 4) control of promotional, marketing and advertising activities. These functions may or may not be undertaken by a single entity (GBT 04).

Key elements of market surveillance and control

Controlling substandard and falsified medicines

Legislation may empower the NRA to recall (or to require the recall of) certain batches of medicines up to the desired point in the supply chain and impose rules regulating the storage, custody and disposal of substandard or falsified medicines to prevent reintroduction into the supply chain (GBT MC01.07). The NRA may issue warnings in national drug bulletins or through specific bodies, associations or key persons that deal with or prescribe pharmaceutical products. The legislation should set out adequate and proportional sanctions and penalties where medicines are found to be false or substandard (GBT MC01.03). Inspections and market surveillance programmes may require sampling and testing of medicines across the supply chain, from the manufacturer through to the distributors and wholesalers and up to the last point of sale or dispensing (including online sales) (GBT MC01.02).

Imports

Legislation can require that imports of medicines be subject to permits (GBT MC01.06) and should establish the decision-making criteria used to evaluate import permit applications (MC04.01). Import controls also require collaboration with customs authorities (GBT MC01.01).

Packaging and labelling

Legislative provisions on registration approval often require applicants to submit proposals for the packaging and labels of the medicines. Legislation should also stipulate substantive rules regarding the packaging of medicines (including information that should appear on the packaging) and information in accompanying patient information leaflets (MA04.08).

Advertising and promotion

Legislation may prohibit the communication of false or misleading information to health professionals, the public, or other stakeholders. Legislative provisions on the advertising and promotion of medicines should align with WHO's *Ethical criteria for medicinal drug promotion* (1988). Legislation may prohibit the advertisement of prescription drugs to the general public and can also place requirements on the content of advertisements that specifically target health-care professionals. Such requirements include consistency between the advertisement and the approved scientific data sheet for the drug concerned or that the advertisement should contain full product information (WHO, 1988). Further legal requirements may be in place for advertising in symposia and medical conferences to allow for the dissemination of scientific information (WHO, 1988). Another important measure is the limitation on handing out free samples of prescription drugs (WHO, 1988).

Questions on market surveillance and control

Core legal elements (MC01.01–MC01.07)

Controlling falsified and substandard medicines

1. With regard to substandard and falsified antimicrobials, does legislation contain provisions for: 1) recall; 2) storage and custody; and 3) destruction and disposal?
2. Is the NRA empowered to issue warnings on substandard and falsified antimicrobials?
3. Does legislation set out sanctions and penalties in cases where antimicrobials are found to be false or substandard?
4. Is there a framework for the NRA to take samples of antimicrobials at different points in the supply chain to test for quality?
 - a. Does this include online sales?

Imports

5. Does legislation require import permits for medicines? Does legislation control imports of medicines? Does this include:
 - a. designation of entry ports through which medicines are imported;
 - b. inspections at designated entry points;
 - c. collaboration with customs authorities?

Packaging and labelling and patient information leaflets

6. Does legislation provide clear minimum standards for: 1) packaging; 2) labelling, and 3) patient information leaflets?
7. Does legislation prohibit or restrict the repackaging of antimicrobials if mixed with other medicines?
8. Does legislation encourage the repackaging of antimicrobials to give the precise dose needed/prescribed?

Advertising

9. Does legislation prohibit the communication of false or misleading information on antimicrobials?
10. Do legal provisions prohibit direct advertising of prescription-only antimicrobials to the public?
11. Does legislation place requirements on the content of advertisements targeting health-care professionals?
12. Does legislation contain provisions governing advertisement and promotion specific to:
 - a. health-care professionals;
 - b. medical representatives;
 - c. medical conferences and symposia?
13. Are there restrictions on the handing out of free samples of antimicrobials?

Sources of international guidance: market surveillance and control

WHO. [Ethical criteria for medicinal drug promotion](#) (1988).

WHO. [Guidelines on packaging for pharmaceutical products](#). Annex 9, WHO Technical Report Series, No. 902 (2002).

WHO. [Guidelines on import procedures for medical products](#). Annex 5, WHO Technical Report Series, No. 1019 (2019).

2.3.8 Pharmacovigilance**Overview**

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems. The scope of pharmacovigilance includes: 1) medication errors; 2) counterfeit or substandard medicine; 3) lack of efficacy of medicines; 4) misuse or abuse of medicines, and 5) interaction between medicines.

Key elements of pharmacovigilance

Legislation may establish the scope of a pharmacovigilance system and set out the entities responsible for various pharmacovigilance functions (both public and private).

Legislation may require these manufacturers and registration holders to set up prescribed pharmacovigilance systems for their medicines, to implement the Good Vigilance Practices (VL01.02) and periodically to report data to the NRA. This system can include requirements to collect, record, store, maintain, evaluate and analyse adverse events (AEs) across the whole medicine lifecycle (VL01.02).

Questions on pharmacovigilance

Core legal elements (VL01.01-VL01.05 + VL01.07)

1. Does legislation establish a national pharmacovigilance system?
2. Does legislation designate the entities responsible for undertaking different pharmacovigilance functions?
3. Does legislation require the manufacturers or registration holders to set up a pharmacovigilance system for their medicines?

Source of international guidance: pharmacovigilance

WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems of medical products. Revision VI, Section 03 – Vigilance (2021).

2.4 Health-care delivery: antimicrobial stewardship through institutions, professionals or insurance schemes

Clinical antimicrobial stewardship refers to the careful and responsible management of antimicrobials in clinical settings (WHO, 2019). Both the provision of health care and the dispensing and use of antimicrobials are the responsibility and privilege of health-care professionals and health-care delivery institutions/facilities.

2.4.1 Hospitals and other health-care facilities: licensing and accreditation, infection prevention and control and antimicrobial stewardship

Overview

Hospitals and health-care facilities play a role in managing and treating infectious diseases, preventing the spread of AMR, and optimizing the use of antimicrobials.

Where are hospitals and other health-care facilities regulated?

Health facilities are generally regulated by specific legislation for health-care delivery, which may include in its title “hospitals”, “health/health-care delivery”, “health facility” or “health establishment”. Specific health-care facilities (e.g. care centres for older persons or centres for persons with diabetes) may have specialized legislation. Special legislation may exist for the quality of care, the prevention of health care-associated infections, infection prevention and control (IPC) or antimicrobial stewardship. Self-regulation or private accreditation standards may also (co-)exist and play an important role.

Key elements for provisions on hospitals and other health-care facilities

Health-care facilities are regulated through diverse types of licensing systems and other regulatory requirements. Legislation may establish monitoring mechanisms for IPC and antimicrobial stewardship in different health-care settings. In addition to licensing, there are also independent international quality accreditation programmes for hospitals. A prerequisite for regulation of hospitals and other health-care facilities is the establishment in legislation of a list of public and private health-care facilities, sometimes called a master facility list.

Antimicrobial stewardship and IPC are often the components of minimum quality of care standards, licensing or accreditation programmes, or training requirements. Many countries have specific legislation or provisions for these components in addition to quality of care. Legislation can take various shapes – such as deciding on funding for antimicrobial stewardship, or setting obligatory antimicrobial stewardship structures within hospitals in the form of antimicrobial stewardship teams or programmes. Training programs must be designed to be gender sensitive, catering to the specific educational and professional development needs of all genders. Legislation can also oblige hospitals at

the institutional level (as distinct from the professional/prescriber level) to implement specific interventions regarding prescribing practices.

Legislation may additionally provide minimum standards for the quality of care and equipment. Quality of care would include mechanisms for the prevention of hospital-acquired infections and antimicrobial stewardship. Health-care facilities should have a reporting obligation in cases of an AMR outbreak that severely undermines the continuity of health-care delivery. Legislation may set up a system of inspection, monitoring and surveillance over health-care establishments to ensure that the processes and practices within those establishments meet established requirements.

Questions on health-care facilities

1. Is there legislation that sets out a registration and licensing mechanism for hospitals or other inpatient health-care facilities?
 - a. Does this include private health-care facilities?
 - b. Does this include antimicrobial stewardship requirements?
 - c. Does this include IPC requirements?
2. Is there a (master) list of health-care institutions?
3. Does legislation require licensing for outpatient health-care facilities or physicians' offices?
4. Does legislation contain specific standards for the quality of care in the premises of health-care providers and the equipment used in health-care settings?
5. Are health-care facilities required to report AMR outbreaks that severely undermine the continuity of health-care delivery?
6. Are there antimicrobial stewardship or infection control training requirements for health-care institutions?

Sources of international guidance: hospitals and other health-care delivery institutions

WHO. [Antimicrobial stewardship programmes in health-care facilities in low-and middle-income countries: a WHO practical toolkit](#) (2019).

WHO. [Policy guidance on integrated antimicrobial stewardship activities](#). [Policy guidance on integrated antimicrobial stewardship activities](#). Chapter 5.1: Establish a national coordination mechanism for AMR (2021).

WHO. [Minimum requirements for infection prevention and control programmes](#) (2019).

WHO, UNICEF. [Water, sanitation and hygiene in health care facilities: practical steps to achieve universal access to quality care](#) (2019).

WHO. [Master Facility List Resource Package: guidance for countries wanting to strengthen their Master Facility List](#) (2019).

2.4.2 Health-care professionals and the prescription of antimicrobials and antimicrobial stewardship

Overview

Health-care professionals – and specifically prescribers of medicines – have a major responsibility in the management of AMR and antimicrobial use. Lack of knowledge about AMR, infectious diseases and microbiology, and the appropriate choice of antimicrobials for various infections, all play roles in inappropriate prescribing practices.

Where are health-care professionals and prescription of antimicrobials regulated?

Legislation may regulate all health-care workers or there may be separate legislation for different categories of health-care workers (doctors, nurses, pharmacists, etc.). Trained community health-care workers and informal health-care providers may also each have their own body of legislation. Regulation of professionals in health care is often (co-)regulated by professional self-regulation or private accreditation. Guidelines and protocols for the treatment of (simple) infections may additionally be adopted in separate legislation.

Key elements for provisions for health-care professionals and prescription of antimicrobials***Educational requirements and licensing process***

The requirements relating to the education of health professionals and the maintenance of their competence is subject to diverse oversight mechanisms in different countries. Typically, legislation sets out core requirements for different categories of defined health-care professionals. These requirements may be supplemented (or not) by voluntary or mandatory standards and professional codes of conduct that allow for continued membership. Generally, health-care professionals are required by law to obtain certification via university education. After this, they may have to take another exam to receive a license, either via a governmental institution or a self-regulatory licensing board. The licensing process confers rights and responsibilities on the individual and may also impose penalties for breaches.

Licensing may also be the mechanism through which a health-care professional receives formal education specifically in infectious diseases, antimicrobial stewardship, IPC and AMR. Renewal of licensing can also require continuing professional education in these areas.

Competence to prescribe antimicrobials

Legislation may establish the types of health-care professionals that have the right to prescribe medicines or antimicrobials. Generally, the prescribing of medicines is reserved for physicians. However, in countries where there is a lack of qualified doctors, pharmacists, nurses or community health-care workers may be permitted by law to prescribe medicines or a subset of medicines, including antimicrobials. Some countries allow non-physicians to prescribe certain medicines within their competency, while other countries require a physician's oversight in prescription. Legislation regarding prescriptions might include a requirement for record-keeping of prescriptions issued (including types and amounts) and may also promote best practices such as prescribing medicines on the basis of generic names (WHO, 2021). Formative and continuing education of prescribers as professional training for IPC and antimicrobial stewardship may be required to maintain a licence. In some countries, legislation may prohibit prescribers from dispensing antimicrobials in order to prevent conflicts of interest.

Questions on health-care professionals and prescription of antimicrobials

1. Does legislation require health-care professionals to be in possession of certain education or training specific to the respective category of health professional?
2. Does legislation establish a mechanism for registration or licensing of health-care professionals? If yes, please describe this mechanism.
3. Does the legislative framework include, or allow the possibility of including, elements of antimicrobial stewardship:
 - a. in the formal education of all health-care professionals (physicians/nurses/pharmacists, etc.)?
 - b. as a requirement of continuing professional development for all health-care professionals?
4. Is this continuing professional development that is a requirement for renewal of a licence or of membership of a professional body?
5. Does this system allow for disciplinary oversight and sanctioning health-care professionals?
6. Does legislation restrict which category of professionals can prescribe antimicrobials? If yes, please state which ones.

7. Is there a requirement for health-care professionals to keep records of prescribed antimicrobials?
8. Are prescribers allowed to sell antimicrobials?

Source of international guidance: health-care professionals and prescriptions of antimicrobials

WHO. [The WHO AWaRe \(Access, Watch, Reserve\) antibiotic book](#) (2022).

2.4.3 Pharmacies and other medicine outlets

Overview

Pharmacies and other medicine outlets provide access to antimicrobials. Regulatory control is necessary to ensure access to good-quality medicines by suitably qualified persons.

Where are pharmacies and other medicine outlets regulated?

Some countries have a single law dedicated to pharmacies, while others have an overarching law on medicines and their distribution – of which pharmacies or medicines outlets are a part. Some countries may also gather the different provisions into a code of health or pharmacy (WHO, 2019b).

Key elements of provisions on pharmacies and medicine outlets

Licensing

Medicine may be sold at a variety of different locations depending on their classification – which may be subject to different licensing or authorization processes. Pharmacy licences can be regulated at the federal/national or local levels. Pharmacy licences can be either facility-based or be associated with a specific pharmacist (see in this Tool, section 2.4.4 of this chapter).

Legislation will typically establish a list or register of all (authorized/licensed) pharmacies. In general, the licensing requirements discussed in section 2.3.5 of this chapter should apply to all locations that sell medicines. Legal requirements may limit the sale of prescription-only medicine to certain locations or by certain persons, including officially licensed pharmacies or officially licensed pharmacists. Some countries may allow some low-risk OTC medicine to be sold outside pharmacies, such as in retail stores, while others have legally-mandated monopolies for the sale of all medicines, whether prescription-only or not (WHO, 2019b). Legislation may require all locations that sell human medicine, whether OTC or prescription, to be registered.

Pharmacy services

Legislation may contain a list of pharmaceutical activities and services that can be provided to patients through community pharmacies. In most countries, legislation requires that community pharmacies maintain records of medicines dispensed from a prescription or compounded (WHO, 2019b).

Increasingly, medicines, including some antimicrobials, are sold online. Some countries have authorized the sale of prescription-only medicines over the Internet, while others have excluded (directly or indirectly) medicines from online sales. In countries that allow the sale of medicines online, this activity is usually subject to either prior authorization from the regulatory body or notification of the regulatory body by the pharmacy and may require specific additional rules (WHO, 2019b).

Questions on pharmacies and other medicine shops

1. Does legislation provide for the licensing of pharmacies?
2. Does legislation restrict the sale of antimicrobials or medicines that require prescriptions to certain types of shops or establishments? If so, please describe these shops or establishments (and how they are defined).
 - a. Are shops (other than pharmacies) restricted to selling OTC or other category of medicines?
3. Is there a publicly available list of all licensed pharmacies or medicine outlets?
4. Does legislation require pharmacies or other medicine shops to keep records on the sale of prescription medicines?
5. Does legislation regulate online sales of medicines? If yes, is the online sale of prescription-only medicines permitted?

Source of international guidance: pharmacies and medicines outlets

WHO. [Joint FIP/WHO guidelines on Good Pharmacy Practice: standards for quality of pharmacy services](#). Annex 8, WHO Technical Report Series, No. 961 (2011).

2.4.4 Pharmacists, pharmacy workers and other dispensers

Overview

A pharmacist is a trained health-care professional with an important role in the health-care system because of their direct interface with the public. For AMR, these professionals may serve as gatekeepers for access to antimicrobials. Pharmacists, pharmacy technicians, pharmacy assistants and other pharmacy workers or medicine dispensers have varying competencies to sell different types of medicines to the public.

Key elements of provisions on pharmacists and other dispensers

A definition of a pharmacist is very rarely outlined in national legislation. Rather, this role is defined indirectly through educational requirements, which often include having certain university-level education.

Legislation may require licensing or registration of pharmacists. Legislation may establish a public list or registry that contains the names of all registered or licensed pharmacists. Countries may also protect the title of pharmacist in legislation and limit its use to those individuals who are registered or have a licence (WHO, 2019b), with corresponding sanctions (including prosecution) for misuse (WHO, 2019b).

Pharmacists can be assisted by pharmacy technicians or assistants who work under the guidance of a licensed pharmacist (International Standard Classification of Occupations as pharmaceutical technicians and assistants [Code 3213]). Various regulatory options may be in place to authorize a person to practise as a pharmacy technician, with the scope of their responsibilities and degree of autonomy varying widely across jurisdictions. In some countries, the law may allow pharmacy technicians to dispense prescription-only medicines in line with their specific education (WHO, 2019b).

Legislation may allow for disciplinary oversight and sanctions of pharmacists and pharmacy technicians. This may include the obligation to withdraw a licence as the highest disciplinary measure. Continuing education and continuing professional development requirements (by law or as imposed by the relevant self-regulatory body) vary greatly between countries (WHO, 2019b).

Questions on pharmacists, pharmacy technicians and dispensers

1. Does legislation contain educational or training requirements for both pharmacists and other pharmacy technicians? If yes, do the topics include antimicrobial use and AMR?
2. Does legislation establish a list of pharmacists with a professional licence or registration to practice? If yes, is this list to be made publicly available?
3. Does legislation create sanctions against abuse of the pharmacist title?
4. Does legislation create restrictions on non-pharmacist pharmacy workers in the sale or dispensing of prescription-only medicines?
5. Does legislation allow for disciplinary oversight and sanctions for both pharmacists and pharmacy technicians?
6. Does legislation require continuing education of pharmacists?

2.4.5 Licensing of laboratories

Overview

Laboratory analysis is needed to establish conclusively the emergence of AMR. Regulation of laboratories protects the public from substandard and unethical laboratory practices and ensures safe and appropriate quality laboratory operations.

Where are laboratories regulated?

The licensing of laboratories can be found in stand-alone licensing acts, general licensing acts, or in health insurance legislation for health insurance contract-based licensing. Provisions may also be found in standards and metrology legislation or in national standards that incorporate relevant WHO standards, International Standards Organization standards, or private standards from the Clinical and Laboratory Standards Institute.

Key elements of laboratories provisions

Licensing mechanisms for laboratories

Legislation may establish a system for licensing, together with a scheme for inspections to ensure compliance.

Substantive requirements for laboratories

Legislation may require the issuance of guidelines or other documents that establish applicable standards, ideally derived from relevant international standards. Legislation may include minimum requirements for the operation of laboratory equipment, procurement and laboratory personnel. Legislation can also mandate quality management and link certification and accreditation requirements and participation in external quality assessment programmes to the licensing process. Where certification or accreditation is not a requirement for licensing, the legislation itself can directly define the minimum criteria for an adequate quality management system.

Questions on laboratories

1. Is there a framework for the licensing of health laboratories? If yes, please describe.
2. Does legislation require the issuance of minimum quality standards, or a basic quality management system for laboratories?
3. Does legislation prescribe minimum requirements for:
 - a. education/qualifications of the head of the laboratory;
 - b. education/qualifications of technical staff with certain functions;
 - c. facilities and equipment?

2.4.6 Procurement of antimicrobials

Overview

Antimicrobials must be procured in a responsible, transparent and independent manner based on the best price for the best quality. Fairness (and the perception of fairness) are essential to attract the best suppliers and achieve the best prices.

Proper procurement can also relieve some challenges relating to substandard and falsified medicines and medicine shortages.

Where is medicines procurement regulated?

The procurement of medicines may be regulated as part of general procurement legislation or as part of specific legislation for the procurement of medicines.

Key elements of medicines procurement

Medicines procurement agencies may be obliged by law to procure the most cost-effective human medicine in the right quantities (WHO, 1999). This is commonly achieved by: 1) linking procurement to a national list of essential medicines, or the national essential medicine policy, and 2) requiring that procurement standards, such as quality and supply reliability and price, are followed by all public and private actors in the health-care delivery system. Thus, procurement provisions should ensure that: 1) only approved medicines are sourced; and only from 2) approved suppliers; and 3) are distributed by approved entities directly to individuals or entities authorized to acquire such medicines (WHO, 2014).

Questions on procurement

1. Does legislation on procurement establish that:
 - a. only approved medicines are used;
 - b. approved suppliers are used;
 - c. distribution is through authorized entities?
2. Does legislation require:
 - a. use of the national list of essential medicines or the national essential medicine policy;
 - b. adherence to national procurement standards (concerning quality and supply reliability as well as price) by public and private actors in the health-care delivery system?

Source of international guidance: procurement

WHO. [Model quality assurance system for procurement agencies](#). Annex 3, WHO Technical Report Series, No. 986 (2014).

2.4.7 Medical waste management and disposal of medicines

Overview

Waste from antimicrobials and antimicrobial-resistant microorganisms poses significant risks for the development of AMR, particularly where these wastes, often from the manufacturing of medicines, or from hospitals or households, end up in water sources or other environmental media (see in this Tool, Chapter 7).

Where are medical waste management and disposal of medicines regulated?

A national law on medical waste management may stand alone or constitute part of comprehensive legislation on waste (including hazardous wastes), hospital hygiene and infection control, or medicines.

Key provisions on medical waste and disposal of medicines

Legislation can identify different medical waste categories and establish specific rules for segregation, collection, storage, handling, transport, treatment and disposal. Legislation may establish responsibilities, training requirements, record-keeping and reporting duties for actors along the waste management chain. Chapter 7 of the Tool provides further information on legislative provisions relating to permitting or licensing for waste management.

Households can also be a source of medical waste. Legislation may contain requirements for consumers to dispose of their waste properly or may require that the medicine label or package indicates the appropriate disposal method. A common mechanism is to require the return of unused or expired medicines, potentially explicitly including antimicrobials, to specified locations for further treatment and disposal.

Questions on medical waste management and disposal of medicines

1. Does legislation include requirements relating to the disposal of medicines? If yes, does this include antimicrobials?
2. Does legislation address the management of medical waste?
3. Does legislation address household disposal of medicines?
4. Is there legislation that creates responsibilities for health-care facilities and pharmacies to dispose of antimicrobials properly?

Source of international guidance: medical waste

WHO. [Safe management of wastes from health-care activities: a summary](#) (2017).

2.5 Surveillance of antimicrobial use and AMR

Overview

Surveillance of AMR and antimicrobial use is key to informing and assessing the impact, and monitor the outcomes of interventions.

Where can this be regulated?

Surveillance of antimicrobial use and AMR may be found in medicine laws or in laws on infectious or communicable diseases, emergency response or public health.

Key elements for surveillance mechanisms

Legislation may establish a surveillance system for public health and for certain diseases. Legislation should designate the competent authorities tasked with designing and implementing the system. This may involve the development of a surveillance plan that includes: methods, infrastructure and mechanisms for data collection; access to use and sales data; and microbiology laboratory diagnostics, analysis and sharing among national and international institutions. Such a plan may be used to introduce elements that are specific to AMR. Regulations may require the use of information technology for data-sharing between the surveillance mechanism and health-care facilities, including between countries or with international surveillance systems such as the WHO Global Antimicrobial Resistance and Use Surveillance System (GLASS).

Questions on monitoring and surveillance

1. Does legislation establish a monitoring and surveillance system? Does this currently, or could it potentially, include AMR and antimicrobial consumption/use?
2. Does legislation identify the competent authority or authorities responsible for managing and implementing the system?
3. Does legislation enable and require harmonization in monitoring and reporting certain types of data? If yes, does this or could this potentially include data on antimicrobial use and AMR?
4. Is there legislation requiring record-keeping and data-sharing or annual reporting on antimicrobial use by public health authorities?
5. Does legislation allow for cross-border data-sharing of health data?

References for Chapter 2

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Chapter 3

Food safety



3.1 Relevance of food safety to addressing AMR

Overview

Antimicrobial-resistant microorganisms or antimicrobial residues are a food safety hazard, although risks vary among different microorganisms as well as in different regions (FAO/WHO, 2021). Food products (particularly raw foods) may be contaminated with microorganisms that have gained resistance to antimicrobials. The consumption of certain antimicrobial-resistant microorganisms in food may cause illness, and these and other species may also become sources of transferable resistance determinants for other microorganisms, including human pathogens (FAO/WHO, 2021). Other substances used to control microorganisms – such as pesticides in crops, feed and feed ingredients, and residues from veterinary medicinal products (VMPs) in animal source food – may be consumed by humans or food-producing animals.

Note on the use of Chapter 3

Food safety is a cross-cutting topic that involves activities along all stages of the food production chain, from primary production of animals and plants to preparation and consumption by consumers. Consequently, unlike other chapters in this Tool, a sound assessment of the national legislation relevant to food safety is linked to the other chapters – particularly chapters 2, 4 and 5.

Where is food safety regulated?

Food safety legislation is often found in self-standing food safety (and quality) laws. Legislation on food safety may also be included in laws covering a wider field of application such as food and drugs (and possibly cosmetics). Relevant provisions for assessing AMR concerns in food may be found in other types of laws, including agriculture and animal health laws, import and export laws, business laws, or more general laws on product safety and consumer protection. Similarly, some countries address food safety through broader public health legislation that may cover some or all stages of the production chain.

3.2 General elements of a food safety legal framework

This preliminary section provides an overview of the food safety framework in very broad terms in order to address only the points in the food chain that are relevant to AMR.

Institutional framework

Legislation should clarify which authority is (or which authorities are) competent to regulate, monitor and control food safety, including the approval of food safety and quality standards. Food safety may be under the mandate of one body exclusively (a food safety agency), or multiple bodies in different agencies, or at different levels of government (i.e. central

or federal and decentralized or local). Where more than one institution has competence over food safety, a single entity should be assigned ultimate responsibility for coordination and oversight for all food safety matters across the entire food chain (Codex Alimentarius *Principles and Guidelines for National Food Control Systems* [CXG 82-2013]). Legislation may empower the authority responsible for food safety to designate and regulate reference laboratories and official laboratories (CXG 82-2013).

Scope

To ensure that no gaps arise in the food safety control system (and thus to take into consideration all possible stages at which AMR risks occur), legislation should follow the whole food chain approach (CXG 82-2013, principle 2) so that it applies to all food businesses at all stages of production and distribution, including the production of farm inputs such as feed for food-producing animals (i.e. “from farm to fork”).

Food safety measures and principles

Food safety measures (including legislation) should be based on international standards – specifically those issued by the Codex Alimentarius Commission (CAC). Food safety legislation should be based on risk analysis, and the competent authorities should be empowered to carry out risk assessments regarding the fitness of products for human consumption, to manage and communicate risks and to approve and implement food safety measures. Legislation should prohibit the distribution of food that is unsafe. Legislation should define unsafe food in terms of potential harm to human health. These general provisions are useful legislative entry points under which to address risks that arise from antimicrobials and antimicrobial-resistant microorganisms.

Food business operators

Legislation should place the primary responsibility for food safety on food business operators (FBOs) involved in producing, processing and distributing the food or in any other step in the food chain (CXG 82-2013). One of the mechanisms for controlling FBOs is the requirement of registration or a licence to operate issued by the competent authority for food.

Questions on general elements

Institutional framework

1. Where is food safety regulated? Are different aspects of the food chain covered by different laws?
2. Does legislation establish:
 - a. a single competent authority that governs food safety across the entire food chain from farm to fork;
 - b. multiple authorities to be responsible for food safety across the food chain?
3. Do(es) the competent authority(ies) have the mandate to approve, monitor and control food safety and quality standards?
4. Does the competent authority have a legal mandate to designate and regulate reference and official laboratories?

Food safety measures and principles

5. Does legislation give the competent authority(ies) the power to approve and implement food safety measures to contain potential food safety hazards?
6. Does legislation require food safety measures to be based on risk analysis?
7. Is there a general prohibition against the distribution of food that is not safe or that is unfit for human consumption?

Food business operators

8. Does legislation recognize the primary responsibility of FBOs for food safety?
9. Does legislation require FBOs to obtain a licence to operate?

Sources of international guidance on general food safety frameworks

FAO/WHO *Codex Alimentarius*

Principles and guidelines for national food control systems (CXG 82-2013 and CXG 91-2017).

Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CXG 77-2011).

CAC Procedural Manual, Twenty-eight edition, revised (2023).

Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance (CXC 61-2005).

Guidelines on integrated monitoring and surveillance of foodborne antimicrobial resistance (CXG 94-2021).

3.3 Food safety objectives

A food safety objective is the maximum frequency and/or concentration of a hazard in a food at the time of consumption within the appropriate level of protection (FAO/WHO, 2023). Food safety objectives encompass maximum limits of contaminants; maximum residue limits (MRLs) for pesticides, veterinary medicinal products (VMPs, although CAC refers to these substances as veterinary drugs) and microbiological criteria. MRLs are a regulatory mechanism for controlling the residues of antimicrobials.

3.3.1 Pesticide and VMP MRLs

Overview

The consumption of foods from animals that have been treated with VMPs may be a source of exposure to antimicrobials. This is particularly the case where the withdrawal period between treatment and slaughter of the food-producing animal has not been respected. Similar risks are observed in relation to pesticides.

Antimicrobial residues may also contribute to further exposure of microorganisms that may develop AMR, while the residue itself may contribute to developing resistant microorganisms that move through the food chain, potentially including consumption as food by consumers.

Where can MRLs be regulated?

MRLs are usually addressed in legislation on food safety or public health. Legislation on VMPs may include references to MRLs. MRL provisions for VMPs may also be found in legislation on animal health, aquaculture or animal production. MRLs for pesticides are sometimes included with legislation on pesticides management or agricultural production.

Key elements for MRLs

Legislation should require that acceptable maximum levels of pesticide and VMP residues in food and feed crops be established; these may be found in different provisions and even different laws. MRLs will be established in distinct food standards which set out the quantitative limits for the different types of residues. The Codex Alimentarius defines MRLs for VMPs and for pesticides (FAO/WHO, 2023). Legislation may expressly require the observation of withdrawal periods prior to slaughter and the harvesting of animal products (meat, milk or eggs) from treated animals.

Questions on pesticide and VMP MRLs

1. Does legislation identify the authority responsible for:
 - a. issuing, establishing or setting the MRLs for:
 - i. pesticides;
 - ii. VMPs;
 - b. monitoring and enforcing the MRLs (e.g. through inspections, testing, etc.)?

2. Are the MRLs based on the relevant CAC standards?
3. Does legislation prohibit the sale of food that exceeds:
 - a. the pesticide MRL;
 - b. the VMP MRL?
4. Does legislation require the observance of withdrawal periods?

Sources of international guidance on pesticides MRLs

FAO/WHO *Codex Alimentarius*

Recommended methods of sampling for the determination of pesticide residues for compliance with MRLs (CXG 33-1999).

Guidelines on Good Laboratory Practice in pesticide residue analysis (CXG 40-1993).

Principles and guidance on the selection of representative commodities for the extrapolation of maximum residue limits for pesticides to commodity groups (CXG 84-2012).

Guidelines on performance criteria for methods of analysis for the Determination of Pesticide Residues in Food and Feed (CXG 90-2017).

Codex Pesticides Residues in Food Online Database.

Sources of international guidance on VMP MRLs

FAO/WHO *Codex Alimentarius*

Maximum residue limits (MRLs) and risk management recommendations (RMRs) for residues of veterinary drugs in foods (CXM 2-2023).

Guidelines for the design and implementation of National Regulatory Food Safety Assurance Programme associated with the use of veterinary drugs in food producing animals (CXG 71-2009).

Glossary of terms and definitions (residues of veterinary drugs in foods) (CXA 5-1993).

Codex Veterinary Drug Residue in Food Online Database.

CAC Procedural Manual, Twenty-eight edition, revised (2023).

WOAH *Terrestrial Animal Health Code* (2024): Chapters 3.4, 6.9 and 6.10.

WOAH *Aquatic Animal Health Code* (2024): Chapters 6.2 and 6.3.

3.3.2 Microbiological criteria

Overview

A microbiological criterion is a risk management metric which indicates the acceptability of a food, or the performance of either a process or a food safety control system, following the outcome of sampling and testing for microorganisms, their toxins/metabolites or markers associated with pathogenicity or other traits at a specified point of the food chain (*Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* [CXG 21-1997]).

Where are microbiological criteria regulated?

Microbiological criteria may be found in food standards, food safety or public health legislation, or may form part of provisions relating to hygiene.

Key elements for microbiological criteria provisions

Regulating microbiological criteria involves reducing the levels of pathogens achieved by a given step in food processing, and also establishing the level that is acceptable in a food. Legislation should establish limits on the presence of commensal microorganisms in food throughout its shelf-life, and the competent authority should be empowered to monitor compliance with these limits through inspections and testing.

Question on microbiological criteria

1. Does legislation give the competent authority (or standard-setting authority) the mandate to:
 - a. approve or establish microbiological criteria applicable to food;
 - b. carry out testing and sampling campaigns?

Sources of international guidance on microbiological criteria

FAO/WHO *Codex Alimentarius*

Principles and guidelines for the establishment and application of microbiological criteria related to foods (CXG 21-1997).

Guidelines on integrated monitoring and surveillance of foodborne antimicrobial resistance (CXG 94-2021).

Principles and guidelines for the conduct of microbiological risk management (CXG 63-2007).

3.4 Process requirements for food safety

3.4.1 Food hygiene

CAC has established *General principles of food hygiene* (CXC 1-1969) and several codes of hygiene practice for selected commodities. Legislation should require that food is produced and handled in such way as to ensure food hygiene and to minimize the introduction, presence and growth of microorganisms.

Question on hygiene

1. Does legislation require the use of hygienic practices by FBOs (such as cleaning or disinfection methods in primary production or manufacturing of food, including at slaughterhouses)?

3.4.2 Labelling, traceability and recall

Labels should be in a language that can be easily understood by the consumer. Legislation should require that food labels provide clear information about the identity (name) of the product, the list of ingredients used, the name and address of the manufacturer, etc. (CXS 1-1985). The Codex Alimentarius defines traceability as the ability to follow the movement of a food through specified stage(s) of production, processing and distribution (CXC 1-1969, CXG 60-2006) (FAO/WHO, 2023). As a minimum, legislation should require the keeping of records relating to all those from whom and to whom (other than consumers) a food or ingredient has been supplied. Labelling requirements on food items and obligations regarding lot identification or other identification strategies that identify the producer and the lot are important for traceability.

FAO and WHO define “recall” as action to remove food from the market at any stage of the food chain, including food that is already in the possession of consumers (FAO/WHO, 2019a). Legislation should make FBOs responsible for responding to failures in the food hygiene system (CXC 1-1969). One prerequisite for an effective recall system is the ability to identify FBOs through a unique business identification/registration number. Legislation should state that recalls should be carried out by the FBO, or by the competent authority where the FBO does not comply. Risk communication – for instance, in the form of public warnings – should accompany recall efforts where unsafe products may have reached consumers. Legislation should require documentation and reporting by the FBO to the competent authority on actions taken and results achieved.

Questions on labelling, traceability and recall

1. Does legislation require all packaged food that is sold to bear a label?
2. Does legislation require the establishment of a traceability system?
3. Does legislation require the keeping and sharing of records by the FBOs?
4. Does legislation require a recall when unsafe food has been distributed?
5. Does legislation require public warnings to be issued where unsafe products have reached consumers?

3.5 Surveillance and emergency response

3.5.1 Laboratories and surveillance

The legislation should require the establishment of a system for the monitoring and surveillance of foodborne diseases and incidents (CXC 61-2005). These provisions may be used as entry points in which to introduce AMR parameters for monitoring and surveillance. Legislation should establish the responsibility for FBOs and laboratories to collect, keep and report information relevant to AMR. It may also request the various authorities with a role in AMR to share laboratory surveillance data across various types of surveillance networks and across different ministries (e.g. those responsible for human health, animal health and production, plant health, environment, water, etc.). Legislation should consider data-sharing rules between authorities and for public warnings, as well as the protection of sensitive personal and business data.

Questions on laboratories and surveillance

1. Does legislation establish a national system for monitoring/surveillance of food?
2. Does legislation establish an obligation for laboratories, including private laboratories, to keep and share records with the competent authority?
3. Is the competent authority mandated to:
 - a. share monitoring and surveillance data with other authorities in other sectors;
 - b. protect personal confidential information or sensitive business data (protection of data privacy)?

3.5.2 Emergencies and incident management

Legislation should indicate what constitutes a food safety emergency. Legislation should also require the competent authority to develop an effective and rapid response to incidents, outbreaks and emergencies (large-scale or with significant risk), indicating procedures to be followed in an emergency response plan that provides specific provisions relating to coordination and communication. Legislation may also establish a rapid alert system for the exchange of information (CXG 82-2013/CXG 19-1995).

Questions on emergencies and incident management

1. Does legislation require the competent authority to:
 - a. declare or recommend the declaration of a food safety emergency;
 - b. approve emergency measures;
 - c. coordinate responses to a food safety emergency?
2. Does legislation establish a system for early warning and exchange of food safety information?

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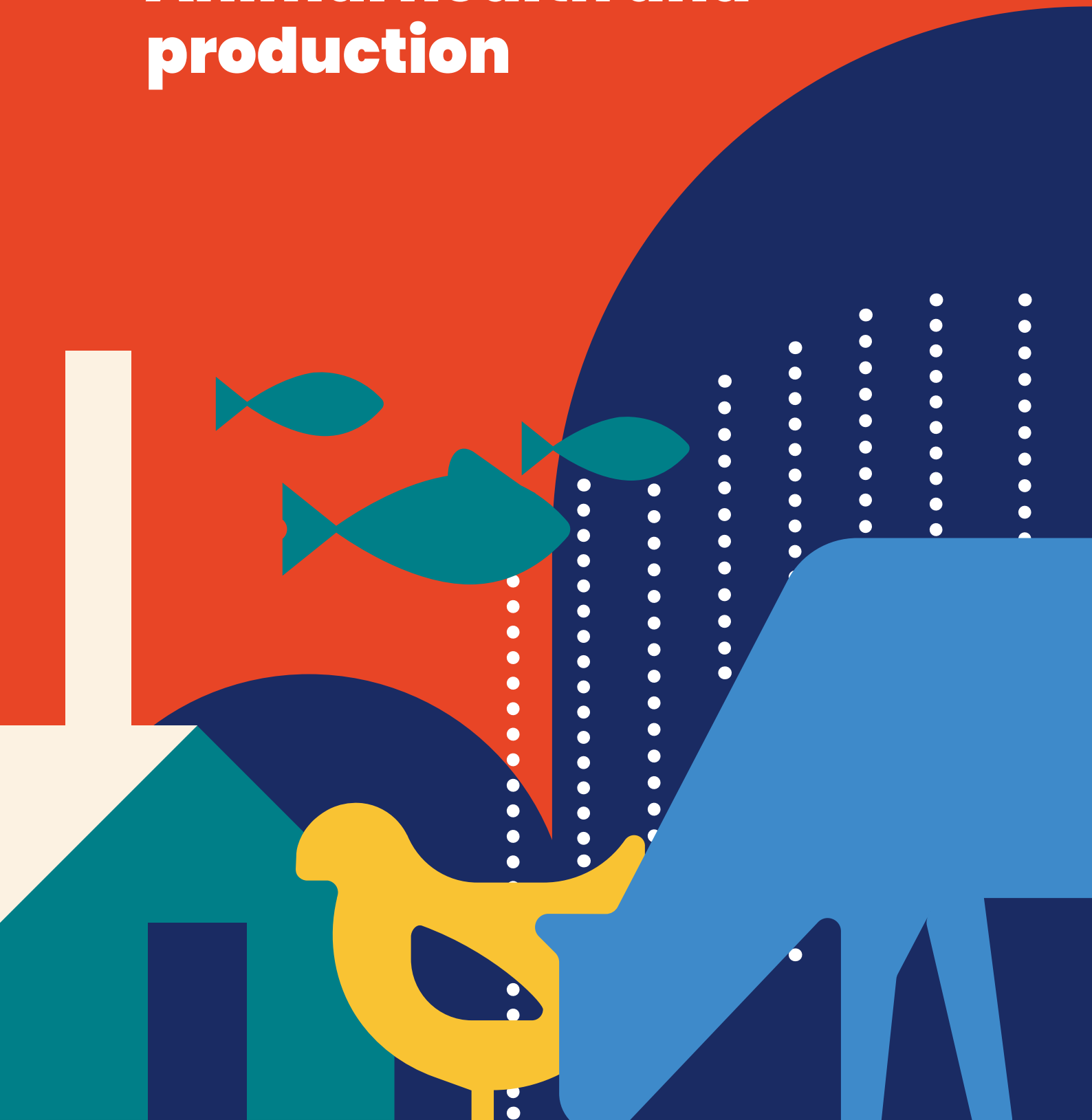
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Chapter 4

Animal health and production



4.1 Introduction

Antimicrobials are used to treat, control and prevent infectious animal disease (i.e. “veterinary medical use”). In some countries these substances are also used for other purposes, including to promote animal growth and production (i.e. “non veterinary medical use”). However, their misuse and overuse combined with weak regulation create opportunities for pathogens to be exposed to antimicrobials and subsequently to develop AMR.

The *Terrestrial Animal Health Code (Terrestrial Code)* and *Aquatic Animal Health Code (Aquatic Code)* of the World Organisation for Animal Health (WOAH) are international reference standards governing animal health and welfare that contain specific standards relating to addressing AMR. According to the *Terrestrial Code*, Article 3.4.11, “veterinary legislation should provide a basis for assuring the quality, safety and effectiveness of veterinary medicinal products and minimizing the risk to human, animal and environmental health associated with their use, including the development of AMR, as described in [*Terrestrial Code*] Chapters 6.7 to 6.11”. Also relevant is the *Codex Alimentarius Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance (Codex CXC 61-2005)*. The elements of national legislation outlined in this chapter and relevant for addressing AMR are sourced from these and other international standards.

Important additional tool: the WOAHP Veterinary Legislation Support Programme (VLSP)

WOAH has a specialized Veterinary Legislation Support Programme (VLSP), which is a component of the Performance of Veterinary Services (PVS) Pathway – WOAHP’s flagship capacity-building platform for the sustainable improvement of national veterinary services. The VLSP aims to assess the compliance of a country’s veterinary legislation with the *Terrestrial Code*, develop recommendations to strengthen the country’s veterinary legislation, and support the revision of existing legislation or the development of specific new laws and regulations.

4.2 Veterinary medicinal products

Overview

An important way to curb the development and spread of AMR is to regulate veterinary medicinal products (VMPs) effectively, including those containing antimicrobials. The ultimate goal of regulating VMPs is to ensure their quality, safety and efficacy, while reducing the potential risks to human and animal health and the environment.

Where are VMPs regulated?

VMPs might be regulated in stand-alone VMP legislation (sometimes called veterinary drugs or veterinary medicines laws); pharmaceuticals/drugs/medicines legislation; animal health or animal production legislation, or fisheries/aquaculture legislation. Some governments regulate human and veterinary medicines in the same laws, while others separate them.

Preliminary observations on VMP legal frameworks: scope and coordination

The primary issue is the scope of laws regulating different types of VMPs (i.e. do they cover both terrestrial animals and aquatic animals), and do they address coordination between VMPs and human medicines. The legal framework for VMPs should be consistent and coordinated between requirements for different types of VMPs, as well as between requirements for VMPs and human medicines.

VMP legislation should identify and outline the functions, powers and mandate of a competent authority to regulate VMPs. Consistency (or lack thereof) in the regime governing human and veterinary medicines may be a result of institutional arrangements. For example, in countries with separate authorities for human medicines and VMPs, it is essential to avoid overlaps or gaps between the responsibilities of the two authorities. One way to do this is to implement a coordinated approval process to reduce the likelihood of conflicting uses. Alternatively, in countries with a single competent authority that regulates both human medicines and VMPs, it is important to ensure there is sufficient veterinary expertise/capacity within that regulatory agency.

Preliminary questions on VMP legal frameworks: scope and coordination

1. Are VMPs regulated together with (in the same legal text as) human medicines?
 - a. If not, is there any overlap created by the definition of the terms “VMP” and “human medicines” (or their equivalents)?
2. Does legislation cover VMPs for both terrestrial and aquatic animals?
3. Does legislation cover the entire lifecycle of a VMP?
4. Does the legislation include definitions of the term “VMP” (or its equivalent)?
 - a. If so, does this align with the definitions provided by the *Terrestrial Code* or the *Codex Alimentarius*?
 - b. Are VMPs part of a broader definition of medicines?
5. Is there a mechanism in legislation (such as a joint body, a requirement of collaboration for registration, or other) to ensure coordination in the following cases (if yes, please describe):
 - a. human medicines and VMPs;
 - b. terrestrial animal VMPs and aquatic animal VMPs?
6. What is (are) the competent authority(ies) for:
 - a. the authorization/registration of VMPs;
 - b. monitoring and enforcing VMP legislation?
7. Does legislation provide a framework for offences and corresponding penalties?
8. Does legislation include a provision on the designation of laboratories (public or private, inside or outside the country) to test VMPs for quality, safety and efficacy and to identify substandard or falsified VMPs?

Sources of international guidance on VMPs: Legal frameworks

WOAH *Terrestrial Animal Health Code* (2024): [Glossary](#) and Chapters 3.4 and 6.10.

WOAH *Aquatic Animal Health Code* (2024): [Glossary](#) and Chapter 6.2.

FAO/WHO *Codex Alimentarius*

Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance (CXC 61-2005): Section 5.1.

Glossary of Terms and Definitions (Residues of Veterinary Drugs in Foods) (CXA 5-1993).

Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programme Associated with the Use of Veterinary Drugs in Food Producing Animals (CXG 71-2009).

4.2.1 Authorization/registration

Overview

The authorization (or registration) stage allows for a determination on which VMPs will be authorized for sale and use on the domestic market. This process is thus useful to control *which* antimicrobials are authorized for use in the veterinary sector, and *how* they can be used.

Where are authorisation/registration regulated?

Authorisation/registration may be regulated through VMP legislation; pharmaceuticals/drugs/medicines legislation; animal health or animal production legislation, or fisheries/aquaculture legislation.

Key elements of provisions on authorization/registration

Legislation should stipulate that any VMP that is not authorized or registered is prohibited from distribution and use in the country, except for specified exemptions such as for emergencies or research (Codex CXC 61-2005, principle 9). The competent authority should have effective regulatory control for the market authorization of VMPs (*Terrestrial Code*, articles 3.2.9 and 3.4.11). Where multiple authorities are involved in VMP authorization, the process should be coordinated in legislation. Similarly, where a single authority is mandated to authorize VMPs and this is not the veterinary authority, the input of other relevant entities (which notably allows for the contribution of veterinary expertise) should be required by law before granting an authorization.

Authorized VMPs are recorded in a national list or registry, which may include specialised categories of products, such as VMPs authorized only for limited or restricted uses.

To support countries in managing the risks associated with antimicrobial use, WHO and WOAH developed lists of antimicrobials in the human health and animal health sectors, respectively: the WHO *List of Medically Important Antimicrobials* (WHO MIA List) – previously known as the WHO *List of Critically Important Antimicrobials for Human Medicine* (WHO CIA List) – and the WOAH *List of Antimicrobial Agents of Veterinary Importance*.

Questions on the VMP authorization/registration framework

1. Does legislation prohibit the production, importation, distribution, sale and use of VMPs that are not authorized/registered?
 - a. Are there exceptions to the rule? Please describe.
2. Does legislation require any coordination in the authorization/registration of VMPs and human medicines? (Please describe any coordination mechanism or other process which allows for the contribution of veterinary expertise if there is a single body responsible for registration.)

3. Are there any provisions to restrict the authorization and use in the veterinary sector of antimicrobials that are critically important for human medicine? If yes:
 - a. Are those provisions based on the WHO *List of Medically Important Antimicrobials* and the WOAHA *List of Antimicrobial Agents of Veterinary Importance*?
 - b. Is there a coordination process such as joint authorization between animal health and human health competent authorities?
4. Does legislation require the competent authority to approve and maintain/update a list/registry of VMPs?
5. Does legislation require authorized VMPs to be classified according to:
 - a. typology and potential hazard;
 - b. dispensing requirements (prescription and supply)?

Sources of international guidance on VMPs: Authorization/registration

WOAH *Terrestrial Animal Health Code* (2024): Chapters 3.2, 3.4 and 6.10.

WOAH *Aquatic Animal Health Code* (2024): Chapter 6.2.

FAO/WHO *Codex Alimentarius Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance* (CXC 61-2005): Section 4.

WOAH *List of Antimicrobial Agents of Veterinary Importance* (2024).

WHO *List of Medically Important Antimicrobials* (WHO MIA List) (2024).

4.2.2 Packaging and labelling

Overview

Packaging means the container and the protective wrapping around individual units, and labelling means the information displayed on the product or its packaging. Labels are an essential tool to promote the responsible and prudent use of VMPs.

Where are packaging and labelling regulated?

Packaging and labelling may be regulated through VMP legislation; pharmaceuticals/drugs/medicines legislation; animal health or animal production legislation, or fisheries/aquaculture legislation.

Key elements of provisions on packaging and labelling

Legislation should require that approval of the packaging and labelling of a VMP be part of the VMP authorization/registration process. VMP legislation should also provide the legal basis for the government to monitor compliance with packaging and labelling requirements established in legislation and approved during registration.

First, labels should be comprehensible to users: therefore, where locally applicable, legislation should require a label or insert in the country's official language(s). Legislation should require that labels: include serial numbers or authentication marks; contain information on the species of animals in which use is allowed and specify dosage and treatment duration (with specific directions in the case of VMPs containing antimicrobials); and contain the expiry date and use instructions, including withdrawal periods and safety warnings.

Questions on packaging and labelling provisions

Packaging

1. Does legislation prohibit putting VMPs on the market unless they meet packaging requirements?
2. Does legislation prohibit or restrict repackaging of VMPs?

Labelling

3. Where locally applicable, does the legislation require that labels be printed in the official language(s) in order to be understandable to users?
4. Does legislation require the label to include information, such as serial numbers or authentication marks, to combat unregistered or falsified VMPs from entering the market?
5. Does labelling legislation require that the following recommended information be included on the (outer) packaging and/or accompanying leaflet:
 - a. active ingredient and class;
 - b. authorized use, including the animal species (and age and/or production category, as appropriate), indications, dosage regimen and administration route;
 - c. withdrawal periods;
 - d. conditions of use relevant to the potential for selection of resistance;
 - e. expiration date;
 - f. rules on disposal;
 - g. external label warnings that sale or administration requires a prescription;
 - h. permitted off-label use(s), if any, or the prohibition of off-label uses where appropriate?

Sources of international guidance on VMPs: Packaging and labelling

WOAH *Terrestrial Animal Health Code* (2024): Chapters 3.4 and 6.10.

WOAH *Aquatic Animal Health Code* (2024): Chapter 6.2.

FAO/WHO *Codex Alimentarius Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance* (CXC 61-2005): Section 5.

WHO *Guidelines on packaging for pharmaceutical products*. Annex 9, WHO Technical Report Series, No. 902 (2002).

4.2.3 Operator licensing

Overview

Legislation may require licences issued by the competent authority for different operators involved in activities related to VMPs. Ultimately, this gives the competent authority control over selected activities at various stages of the VMP lifecycle – such as the production, distribution or sale of VMPs.

Where is operator licensing regulated?

Licensing may be regulated through VMP legislation. In some jurisdictions, other licensing requirements may be imposed through general commercial legislation, business licensing laws, or even in specific licensing legislation. Professional boards and the provision of professional services are often regulated under specific legislation.

Key elements of provisions on licensing of operators

Legislation should provide a basis for the licensing of all VMP-related operators, including those engaged in manufacturing, importing, storing, selling or otherwise distributing VMPs, or raw materials used in making VMPs (*Terrestrial Code*, Article 3.4.11). Legislation should require that operators obtain a licence issued according to prescribed criteria and comply with enumerated conditions to maintain the licence. For instance, licensees might be required to report data pertaining to the type and amount of VMPs involved in their activities (e.g. sold, prescribed).

Questions on provisions on licensing of operators

1. Does legislation identify the types of activities in the VMP lifecycle that require possession of a licence (including manufacture, sale and import)?
2. Does legislation impose specific record-keeping and reporting requirements on operators in possession of a licence?
3. Is there a body of inspectors in charge of enforcing the licensing regime?
4. Does legislation create offences and penalties for:
 - a. any activities carried out without a licence where one is required;
 - b. manufacture, sale and import of unlabelled (or incorrectly labelled), substandard, unregistered, falsified or banned VMPs?

Sources of international guidance on VMPs: Operator licensing

WOAH *Terrestrial Animal Health Code* (2024): Chapter 3.4.

FAO/WHO *Codex Alimentarius Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance* (CXC 61-2005): sections 5.1, 5.4 and 5.5.

4.2.4 Manufacturing

Overview

Regulating the manufacture of VMPs serves the twin goals of: 1) safeguarding their quality, safety and efficacy; and 2) controlling discharges into the environment.

Where is manufacturing regulated?

Regulation of the manufacture of VMPs is generally carried out through general VMP legislation. General industrial manufacturing laws and standards may also apply.

Key elements of manufacturing provisions

Legislation should require manufacturers to establish quality assurance systems that incorporate tests on both the raw materials and the final product (Codex CXC 61-2005, section 5.2). Quality controls should be carried out in accordance with the licence requirements as well as with international guidance and general Good Manufacturing Practices (GMP). Legislation may require the adoption of GMP to ensure quality, safety and efficacy.

Question on manufacturing provisions

1. Does legislation require manufacturing of VMPs to the appropriate quality and purity?

Sources of international guidance on VMPs: Manufacturing

WOAH *Terrestrial Animal Health Code* (2024): Chapters 3.4 and 6.10.

WOAH *Aquatic Animal Health Code* (2024): Chapter 6.2.

FAO/WHO *Codex Alimentarius Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance* (CXC 61-2005): Section 5.2.

4.2.5 Import

Overview

In some countries, porous borders lead to the sale and use of large quantities of substandard, unregistered, falsified and even banned VMPs in the domestic market.

Where is import regulated?

Import rules may be included in VMP legislation or in general commercial or trade-related legislation. Legislation may address the import of pharmaceuticals in general or of VMPs in particular.

Key elements of provisions on import

Legislation to control imports of VMPs utilizes a range of mechanisms, including operator licences, import requirements and permits, and inspections. Legislation should require that import control systems be risk-based – i.e. a process that allows for the allocation of scarce resources towards VMPs (and border points) that are considered to be high-risk.

Question on import provisions

1. Does legislation require import permits for VMPs?

Sources of international guidance on VMPs: Imports

WOAH *Terrestrial Animal Health Code* (2024): Chapters 3.4 and 6.10.

WOAH *Aquatic Animal Health Code* (2024): Chapter 6.2.

FAO/WHO *Codex Alimentarius Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance* (CXC 61-2005).

4.2.6 Sale and storage

Overview

According to the WHO definitions (WHO, 2017), “substandard” products are authorized products that do not meet either their quality standards or specifications, or both; “unregistered” or “unlicensed” products are those that have not been evaluated and approved by the regulatory authority, and “falsified” products are those that fraudulently misrepresent the identity, composition or source of the products.

Where are sale and storage regulated?

Sale and storage may be regulated as part of the broader VMP legislation or under general commerce legislation. Environmental law provisions may govern storage. Substandard or falsified VMPs may be regulated under consumer protection legislation.

Key elements of provisions on the regulation of sale and storage of VMPs

Sale

Legislation should prohibit the sale of unlabelled, substandard, unregistered or falsified products. With certain exceptions for emergencies and research, wholesalers, retailers and other points of sale should not be allowed to stock and sell VMPs unless the VMPs are authorized as per the national legislation. Legislation may require the government to issue a licence or permit for any retailer or VMP provider that sells or distributes VMPs containing antimicrobials. The legislation should also provide for effective procedures, such as a mandatory recall system, for the safe collection and disposal of specific lots of unused, substandard, falsified, illegally marketed, or out-of-date antimicrobials (Codex CXC 61-2005, section 5.1).

For countries that classify VMPs according to dispensing requirements established during the registration process (see in this Tool, section 4.2.1), regulations should specify the types of distributors that are authorized to sell particular antimicrobials. In some countries, veterinarians are authorized to sell antibiotics directly. Such a system can be efficient where few pharmacies exist. On the other hand, it requires additional controls, as it opens veterinarians up to potential influence by pharmaceutical companies and other conflicts of interest and may thus incentivize excessive use of antimicrobials. The key is to give the authorities the legal power to monitor sales and establish mechanisms for follow-up after sale.

Storage

Legislation may impose storage requirements on VMP sellers. Legislation should require that the quality of antimicrobials in the marketed dosage form be maintained until the expiry date (established under the recommended storage conditions) and that the stability of antimicrobials be ensured when mixed with feed or drinking-water (*Terrestrial Code*, Article 6.10.3).

Questions on provisions for sale and storage of VMPs

Sale

1. Does legislation restrict the sale of VMPs containing antimicrobials to certain establishments/sellers?
 - a. Is the sale of VMPs containing antimicrobials allowed in:
 - i. pharmacies;
 - ii. veterinary clinics;
 - iii. other establishments (such as feed distributors, supermarkets or pet shops)?
 - b. Is the direct sale of VMPs containing antimicrobials by veterinarians allowed?
 - i. If yes, are provisions in place to prevent conflicts of interest?
2. Does legislation prohibit the dispensing or sale of VMPs containing antimicrobials unless accompanied by a prescription issued by a veterinarian or another authorized prescriber?
3. Are pharmacies and other establishments or professionals that sell antimicrobials legally required to keep and report records of the sale of antimicrobials?
4. Does legislation authorize the sale of VMPs only if they are labelled in accordance with the national legislation?

Storage

5. Are there standards for the storage of VMPs?

Enforcement

6. Are there other specific mechanisms in legislation to prevent and control substandard, unregistered or falsified VMPs?
7. Does legislation grant inspectors specific powers (e.g. to take samples, to enter premises)?
8. Does legislation require inspectors to keep inspection records?

Sources of international guidance on VMPs: Sale and storage

WOAH *Terrestrial Animal Health Code* (2024): Chapters 3.4 and 6.10.

WOAH *Aquatic Animal Health Code* (2024): Chapter 6.2.

FAO/WHO *Codex Alimentarius*

Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance (CXC 61-2005): sections 5.1 and 5.3.

Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programme Associated with the Use of Veterinary Drugs in Food Producing Animals (CXG 71-2009).

WHO *Global Surveillance and Monitoring System for substandard and falsified medical products* (2017).

4.2.7 Prescriptions**Overview**

Legislative provisions on prescriptions help to ensure veterinary oversight of and accountability for the use of antimicrobials. These provisions also facilitate collection of detailed information on VMPs prescribed, which can help governments to understand prescription patterns and can inform the national AMR strategy (see in this Tool, section 4.2.9).

Where are prescriptions regulated?

The VMP legislation itself will often include prescription requirements. Rules on prescriptions may also be found in general animal health laws or legislation governing the practice of veterinary medicine, including the establishment of veterinary statutory bodies. Details may be spelled out in a code of conduct that is binding on veterinarians and other authorized animal health professionals (such as veterinary paraprofessionals [VPPs] and aquatic animal health professionals). Provisions may also be found in pharmacies legislation.

Key elements of provisions on prescriptions

Legislation should require that VMPs containing antimicrobials be prescribed only by veterinarians or other animal health professionals authorized to prescribe such VMPs – all of them referred to in this Tool as “authorized prescribers” (*Terrestrial Code*, Article 6.10.3, and Codex CXC 61-2005, principle 8). Legislation may thus recognise VPPs and aquatic animal health professionals as part of the “authorized prescribers” and stipulate additional conditions under which such authority is granted to them.

Consistent with the *Terrestrial Code* (Article 6.10.6), the *Aquatic Code* (Article 6.2.7) and the Codex CXC 61-2005 (section 5.4), legislation should require that veterinarians and other authorized prescribers be held responsible and accountable for their prescriptions of antimicrobials, and:

- (i) include, in the prescriptions, the detailed treatment protocol, including dosage regimen, precautions and withdrawal periods;
- (ii) prescribe antimicrobials only for animals under their care; and
- (iii) keep records (and retain copies) of prescriptions relating to VMPs containing antimicrobials – and report these data to the competent authority(ies).

Questions on prescription provisions

1. Does legislation prohibit the sale or dispensing of antimicrobials (or a selected list of antimicrobials) without a prescription?
2. Does legislation specify that VMPs containing antimicrobials should be prescribed only by veterinarians or other authorized prescribers?
3. Does legislation require authorized prescribers to include, in the prescriptions, the detailed treatment protocol, including dosage regimen, precautions and withdrawal periods?
4. Does legislation require authorized prescribers to prescribe antimicrobials only for animals under their care?
5. Does the legislation require that authorized prescribers keep records of prescriptions relating to VMPs containing antimicrobials and report these data to the competent authority(ies)?
6. Does legislation give the competent authority the power to collect and share antimicrobial prescription-related data?

Sources of international guidance on VMPs: Prescriptions

WOAH *Terrestrial Animal Health Code* (2024): Chapters 3.4 and 6.10.

WOAH *Aquatic Animal Health Code* (2024): Chapter 6.2.

FAO/WHO *Codex Alimentarius Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance* (CXC 61-2005): sections 4 and 5.4.

WOAH *List of Antimicrobial Agents of Veterinary Importance* (2024).

WHO *List of Medically Important Antimicrobials* (WHO MIA List) (2024).

4.2.8 Administration and use

Overview

The responsible and prudent use of antimicrobials in the animal health sector involves taking practical measures to improve animal health and welfare, while preventing or reducing the selection, emergence and spread of AMRs in animals, humans and the environment (*Terrestrial Code*, Article 6.10.2, *Aquatic Code*, Article 6.2.2, and Codex CXC 61-2005, principle 6).

Where are administration and use regulated?

Administration and use may be regulated in animal health or biosecurity legislation, VMP legislation, aquaculture production legislation, agricultural production legislation or in legislation on the provision of veterinary services (including codes of conduct).

Key elements of administration and use provisions

Countries may set up legislative provisions restricting or prohibiting non veterinary medical uses of antimicrobials (such as for growth promotion or to increase productivity):

- (i) in the absence of risk analysis (as recommended by the Global Action Plan on AMR and WOAH *List of Antimicrobial Agents of Veterinary Importance* – see in this Tool, section 4.2.1); and
- (ii) fully prohibiting the use, as growth promoters, of the fluoroquinolones, colistin and third and fourth generations of cephalosporins (as recommended by the WOAH List), as these are highest priority critically important antimicrobials according to the WHO *List of Medically Important Antimicrobials*.

In the framework of the *Terrestrial Code* (Article 6.10.3) and Codex CXC 61-2005 (principle 8 and sections 5.4 and 5.5), legislation should also require that VMPs containing antimicrobials be administered to animals by, or under the supervision or by direction of, a veterinarian or another authorized animal health professional.

Veterinarians and other authorized animal health professionals

Consistent with the *Terrestrial Code* (Article 6.10.6), *Aquatic Code* (articles 6.2.7 and 6.2.9) and Codex CXC 61-2005 (section 5.4), legislation should require that the veterinarians and other authorized animal health professionals (such as VPPs and aquatic animal health professionals):

- (i) administer antimicrobials in accordance with the specifications of the marketing authorization;
- (ii) keep records of the antimicrobials they administer or that are administered under their supervision/direction (in particular, the name of the product, name and concentration of the antimicrobial active substance[s], types and amounts of antimicrobials and package size) and report these data to the competent authority(ies), and
- (iii) undertake training on the use – and preservation of effectiveness – of antimicrobials (many jurisdictions require continuing education for veterinarians as part of renewing their licences).

Animal producers

Consistent with the *Terrestrial Code* (Article 6.10.8), *Aquatic Code* (articles 6.2.8 and 6.2.9) and Codex CXC 61-2005 (section 5.5), legislation should set out the responsibilities of livestock and aquaculture producers regarding:

- (i) compliance with label instructions (including withdrawal periods) and the instructions of the authorized prescriber;
- (ii) the use of antimicrobials only on the prescription of an authorized prescriber (see in this Tool, section 4.2.7);
- (iii) record-keeping of antimicrobials used (in particular, the name of the product, name and concentration of the active antimicrobial substance[s], types and amounts of antimicrobials, package size, number of animals treated, animal species targeted, weight of animals treated) and reporting of these data to the competent authority(ies); and
- (iv) the sound disposal of waste material as well as expired and unused surplus VMPs containing antimicrobials under conditions safe for the environment to minimize the development and spread of AMR.

Off-label uses

Legislation should also address off-label (or “extra-label”) uses of VMPs – i.e. their uses in a manner that is not approved in the registration or set out on the label. Such extra-label uses include varying the dosage or route of administration, often for purposes of treating a different disease or animal species/type than that for which the VMP is normally prescribed. Legislation may allow off-label uses of antimicrobials but, if so, it should describe the situations in which such uses are permitted and the rules that should be followed.

Questions on administration and use provisions

1. Does legislation require VMPs containing antimicrobials to be administered to animals by, or under the supervision or by direction of, a veterinarian or another authorized animal health professional?
2. Is there a prohibition or restriction on using antimicrobials for non veterinary medical purposes, such as for growth promotion or increased productivity, notably in the absence of risk analysis?
3. Does legislation require that veterinarians and other authorized animal health professionals administer antimicrobials in accordance with the specifications of the marketing authorization?
4. Are there any provisions that allow off-label or extra-label use of VMPs? If so, are any conditions established?
5. Does legislation require veterinarians and other authorized animal health professionals to keep records of the antimicrobials they administer or that are administered under their supervision/direction (in particular, the name of the product, name and concentration of the antimicrobial active substance[s], types and amounts of antimicrobials and package size) and to report these data to the competent authority(ies)?
6. Does legislation require that animal producers:
 - a. use VMPs in accordance with label instructions (including withdrawal periods) and the instructions of the authorized prescriber;
 - b. keep records of antimicrobial use (in particular, the name of the product, name and concentration of the active antimicrobial substance[s], types and amounts of antimicrobials, package size, number of animals treated, animal species targeted, weight of animals treated)?
7. Does legislation give the competent authority the power to collect and share antimicrobial use-related data?

Sources of international guidance on VMPs: Administration and use

WOAH *Terrestrial Animal Health Code* (2024): Chapters 3.4, 6.9 and 6.10.

WOAH *Aquatic Animal Health Code* (2024): Chapters 6.2 and 6.3.

FAO/WHO *Codex Alimentarius*

Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance (CXC 61-2005): sections 4, 5.4 and 5.5.
Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CXG 77-2011).

WOAH *Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials* (2016).

WOAH *List of Antimicrobial Agents of Veterinary Importance* (2024).

WHO *List of Medically Important Antimicrobials* (WHO MIA List) (2024).

4.2.9 Pharmacovigilance and post-marketing surveillance

Overview

Pharmacovigilance consists of the collection of data on – and the detection, assessment, monitoring and prevention of – adverse effects of pharmaceuticals. The *Terrestrial Code*, *Aquatic Code* and Codex CXC 61-2005 all recommend that governments establish pharmacovigilance programmes. The defining feature of pharmacovigilance is that it focuses on the effects of VMP use even when all regulatory requirements are fulfilled throughout the market chain.

Post-marketing surveillance is another essential tool for detecting and mitigating the negative effects of VMPs. It may include AMR monitoring and surveillance programmes.

The collection, sharing and interpretation of antimicrobial-related data should be supported by a strong regulatory framework, including: legal obligations for VMP operators and users to record and report data; allowing the competent authority to collect, share and interpret these data; and supporting pharmacovigilance/post-marketing surveillance.

Important additional tool: the WOAH global database ANImal antiMicrobial USE – ANIMUSE

In the framework of the Global Action Plan on AMR, WOAH has built a global database on antimicrobials intended for use in animals (ANImal antiMicrobial USE = ANIMUSE).

A strong national regulatory framework which facilitates the collection and interpretation of antimicrobial-related data thus not only serves countries, but also allows them to report to WOAH ANIMUSE. This in turn allows countries to have ownership of their data to report, consult, analyse and communicate to national stakeholders while having confidential access to the centralized IT system.

Where are pharmacovigilance and post-marketing surveillance regulated?

Pharmacovigilance reporting requirements for operators may be covered in VMP/pharmaceuticals legislation, veterinary practice legislation, and general commercial legislation. Post-marketing surveillance may be addressed in general pharmaceutical legislation, VMP legislation or animal health and disease control legislation. AMR monitoring and surveillance programmes may be addressed in general pharmaceuticals legislation, VMP legislation or animal health and disease control legislation.

Key elements of pharmacovigilance provisions

Under a pharmacovigilance system, each operator in the VMP lifecycle is required to report to the competent authority any actual (or in some cases, suspected) incidences of adverse effects, including lack of response due to possible AMR. Such reporting may come from different sources, such as manufacturers through Periodic Safety Update Reports (PSURs), veterinarians and other authorized animal health professionals informing the competent authority of an adverse effect after using the product (*Terrestrial Code*, Article 6.10.6, *Aquatic Code*, Article 6.2.7, and Codex CXC 61-2005, section 5.4), and animal producers.

Key elements of post-marketing/AMR monitoring and surveillance provisions

Legislation may establish general data collection and analysis provisions for monitoring and surveillance. Unless restrictively worded, general enabling provisions are sufficient for programmes that seek to gather data to determine trends and sources of AMR as well as other types of data. Legislation may make provision for data to be shared under other surveillance programmes that may be implemented at national level (such as programmes for human health, environmental purposes or AMR-specific surveillance schemes).

Post-marketing/AMR monitoring and surveillance programmes may also have a legislative basis.

Questions on provisions on pharmacovigilance and post-marketing surveillance

1. Does legislation require the establishment of a pharmacovigilance system for VMPs? If yes, does it include reporting on adverse effects?
2. Does legislation provide for a system of post-marketing surveillance to control the safety and efficacy of VMPs?
3. Does legislation allow for the sharing of pharmacovigilance and post-marketing data with other authorities responsible for health?

Sources of international guidance on VMPs: Pharmacovigilance and post-marketing surveillance

WOAH *Terrestrial Animal Health Code* (2024): Chapters 3.4, 6.8, 6.9 and 6.10.

WOAH *Aquatic Animal Health Code* (2024): Chapters 6.2, 6.3 and 6.4.

FAO/WHO *Codex Alimentarius*

Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance (CXC 61-2005): sections 4, 5.1 and 5.4.
Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance (CXG 94-2021).

WOAH. *How to set up a pharmacovigilance system for veterinary medicinal products* (2022).

4.2.10 Disposal and destruction

Overview

Antimicrobials that are disposed of improperly may enter the environment, where they can contribute to the development of resistance. Chapter 7 of the present Tool explores the environmental dimensions of AMR.

Where are disposal and destruction regulated?

Generally, disposal and destruction of VMPs are regulated in VMP legislation, although particular provisions in environmental legislation, waste management legislation, water legislation and land use legislation may also apply.

Key elements of provisions on disposal and destruction

Legislation should provide rules and protocols for the safe collection, disposal and destruction of unused or expired VMPs containing antimicrobials. Legislation may also target all the relevant actors (such as the competent authority, food animal producers, veterinary pharmaceutical industry and veterinarians/authorized animal health professionals) through specific provisions outlining their respective responsibilities, including by requiring their participation in training programmes on this topic. Producers may be required to return unused or expired antimicrobials to the sales or distribution point and/or to follow specific instructions for the safe and proper disposal of antimicrobials.

Questions on provisions on disposal and destruction

1. Does legislation provide rules and protocols for the safe collection and disposal or destruction of unused or expired VMPs?
2. Which actors have legal obligations related to the disposal of VMPs?
 - a. Competent authority(ies)? If so, which one(s)?
 - b. VMP operators? If so, which operator(s) and what are their duties?
 - c. VMP users? If so, what are their duties?

Sources of international guidance on VMPs: Disposal and destruction

WOAH *Terrestrial Animal Health Code* (2024): Chapters 3.4 and 6.10.

WOAH *Aquatic Animal Health Code* (2024): Chapter 6.2.

FAO/WHO *Codex Alimentarius Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance* (CXC 61-2005): sections 5.1 and 5.5.

4.2.11 Advertising

Overview

Because of the potential harmful effects of improper use, particularly with regard to antimicrobials, regulatory authorities should control the advertising of VMPs to ensure that the content complies with the registration/marketing authorization.

Where is advertising regulated?

VMP legislation may include a specific section on advertising; alternatively, general advertising legislation on pharmaceuticals may cover VMPs. Consumer protection legislation may also regulate the advertising of VMPs.

Key elements of provisions for advertising

Legislation should require that advertising and promotion of VMPs be limited to the minimum necessary and be allowed only for purposes of providing medical information. Legislation should prohibit false or misleading claims in advertising.

According to the *Terrestrial Code* (articles 6.10.3 and 6.10.4) and *Aquatic Code* (articles 6.2.4 and 6.2.5), all advertising of antimicrobials should be compatible with the principles of responsible and prudent use, and the relevant authorities should ensure that the advertising of these products: (a) complies with the marketing authorization granted, in particular regarding the content of the summary of product characteristics, and (b) is restricted to veterinarians and other animal health professionals authorized to prescribe antimicrobials. Advertising should not directly target animal producers or the general public.

Questions on advertising provisions

1. Does legislation prohibit false or misleading claims?
2. Is advertising limited to the marketing authorization granted (e.g. is advertising of off-label uses prohibited)?
3. Is advertising restricted to veterinarians and other authorized prescribers?

Sources of international guidance on VMPs: Advertising

WOAH *Terrestrial Animal Health Code* (2024): Chapters 3.4 and 6.10.

WOAH *Aquatic Animal Health Code* (2024): Chapter 6.2.

FAO/WHO *Codex Alimentarius Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance* (CXC 61-2005): sections 5.1 and 5.2.

4.3 Animal feed

Overview

Antimicrobials are added to animal feed to treat and prevent diseases, and also to improve feed efficiency and to boost growth and productivity. The *Codex Code of Practice on Good Animal Feeding* (CXC 54-2004, section 3) defines “medicated feed” as any feed which contains veterinary drugs. Other substances that have an antimicrobial effect, such as copper and zinc, can also be administered to animals through feed.

The present section 4.3 focuses on all legislative rules applicable to feed, feed ingredients and feed additives (including the authorization of additives with antimicrobial properties or additives to be used as alternatives to antimicrobials), as well as specific rules for medicated feed.

Where is animal feed regulated?

Feed can be regulated in stand-alone feed legislation, in food safety legislation, in general veterinary (animal health or production) legislation, VMP legislation, pet legislation or in more general agriculture inputs or agriculture legislation, as well as in fisheries or aquaculture legislation.

4.3.1 Feed management

Key elements of feed legislation provisions

Competent authority and standard setting

Legislation should designate the authority(ies) with competence over the various stages of the feed lifecycle (*Terrestrial Code*, articles 3.4.5, 3.4.8 and 6.4.4, and *Aquatic Code*, articles 4.9.3 and 4.9.6). This can be the veterinary authority or a separate authority. In many countries, fisheries authorities are in charge of feed for aquaculture. Where multiple authorities regulate different aspects of the feed lifecycle, it is important that legislation make provision for coordination among these authorities. Coordination is also necessary between the competent authority for feed and the authorities responsible for VMPs, food safety and, more broadly, animal health and production.

Authorization of feed, feed ingredients and feed additives

Some countries have a system for the authorization/registration of feed, feed ingredients and additives. Other countries may instead require the competent authority for feed to develop lists of authorized (premixed) feed, feed ingredients and feed additives. The lists can be positive (authorized [premixed] feed, feed ingredients and feed additives), negative (prohibited feed, ingredients or additives) or a combination of both.

Whether a country has a full registration procedure or a positive/negative list, it is important that the competent authority have the legal power to prohibit or restrict, at any time, the use of a (premixed) feed product, ingredient or additive if there is new evidence that identifies a risk associated with its use. This power allows the option to include antimicrobials in the categories of what is prohibited or what is restricted.

Labelling and packaging

Feed legislation should establish rules on minimum information to be included on labelling.

Legislation may also restrict any advertising of certain properties or special uses of the product on the label that cannot be verified (or that are not easily verifiable), such as that the product cures or prevents a disease. These restrictions should however be carefully considered as they could hinder the possibility of advertising some substances such as prebiotics or probiotics (that could have beneficial health impacts and reduce the need for antimicrobials).

Feed production processes, traceability and early warning

Legislation should underpin the traceability system for feed, feed ingredients and feed additives. This system is linked to the duty of operators to keep records for timely and effective withdrawal or recall (Codex CXC 54-2004, section 4.3).

Questions on animal feed legislation

Scope of coverage

1. Is there legislation on feed for terrestrial and for aquatic animals?
 - a. Are these regulated in the same law?
 - b. Does the law cover medicated feed?

Competent authority

2. Where multiple authorities are involved (including at different levels of government), is there a mechanism for cooperation or coordination?
3. Is there a regulatory mechanism to approve, authorize, restrict or prohibit the use of additives, substances and ingredients in feed production?

Registration/List

4. Does legislation require the registration or authorization (or establish an approved list) for:
 - a. feed (premixed);
 - b. feed ingredients;
 - c. feed additives?
5. Is there a list of prohibited or restricted
 - a. feed, feed ingredients, additives or substances?

Traceability and recall

6. Does legislation establish a system for the recall of substandard feed?

Sources of international guidance: Animal feed

WOAH *Terrestrial Animal Health Code* (2024): [Glossary](#) and Chapters [3.4](#), [6.4](#) and [6.10](#).

WOAH *Aquatic Animal Health Code* (2024): Chapter [4.9](#).

FAO/WHO *Codex Alimentarius*

[Code of Practice on Good Animal Feeding](#) (CXC 54-2004): sections 3, 4.2, 4.3, 5 and 6.2.

[Guidelines on the Application of Risk Assessment for Feed](#) (CXG 80-2013).

[General Principles of Food Hygiene](#) (CXC 1-1969): Section 8.2.

[CAC Procedural Manual](#), Twenty-eight edition, revised (2023).

4.3.2 Specific framework for medicated feed**Overview**

Medicated feed, which is “any feed which contains veterinary drugs” (Codex CXC 54-2004, section 3), has veterinary medical and non veterinary medical uses.

Where is medicated feed regulated?

Medicated feed may be regulated in stand-alone feed legislation, in food safety legislation, in general veterinary (animal health or production) legislation, VMP legislation, feed additives legislation or in more general agriculture inputs or agriculture legislation, as well as in fisheries or aquaculture legislation.

Key elements of medicated feed legislation provisions

Legislation should distinguish medicated feed from feed that does not contain VMPs. It should include special provisions (*Terrestrial Code*, Article 3.4.11), give the competent authority the power to regulate medicated feed (*Terrestrial Code*, Article 3.2.9) and consider imposing stricter controls on the production, distribution and use of medicated feed. In fact, in some countries, medicated feed may fall within the definition of a VMP and may thus be subject to the same rules as other VMPs – e.g. rules regarding the labelling, storage, sale, prescription, use, record-keeping/reporting and disposal as other VMPs. Additional rules may be applicable (e.g. medicated feed should be stored and transported in a manner that prevents accidental spills and cross-contamination with other medicated feed or with non-medicated feed [Codex CXC 54-2004, sections 5.6 and 6.3.3]).

Consistent with the WOA *Terrestrial Code* (articles 6.10.3 and 6.10.7), specific rules may apply to medicated feed containing antimicrobials. Legislation should notably:

- (i) specify requirements in terms of labelling;
- (ii) specify that such medicated feed should be prescribed only by veterinarians, or other animal health professionals authorized to prescribe VMPs containing antimicrobials;
- (iii) prohibit the dispensing or sale of such medicated feed unless accompanied by a prescription issued by an authorized prescriber;
- (iv) require that such medicated feed (or water) be administered to animals under the supervision or by direction of a veterinarian or another authorized animal health professional; and
- (v) that manufacturers of medicated animal feed undertake training on the use of antimicrobials.

Legislation should require that, where a VMP has been added to feed, such medicated feed should be registered as a VMP; this would lead to consistent regulation of VMPs and medicated feed. Furthermore, legislation should designate the competent authority for medicated feed and establish its relationship with the other competent authorities responsible for VMPs in order to create a coordinated institutional framework.

Questions on the framework for medicated feed

1. Does the definition of VMP include medicated feed?
2. Is there a definition of medicated feed?
 - a. Does this definition include (or expressly exclude) all or some antiparasitics?
3. Does legislation designate one or more competent authority(ies) responsible for the monitoring and enforcement of medicated feed legislation?
4. Is there a framework for collaboration established among the competent authority(ies) for medicated feed and the authorities responsible for:
 - a. VMPs (where this is regulated separately);
 - b. human medicines?
5. If not defined as a VMP, is medicated feed subject to requirements similar to those that apply to VMPs for:
 - a. authorization/registration;
 - b. production/manufacturing;
 - c. labelling;
 - d. advertising;
 - e. storage;
 - f. sale;
 - g. import;
 - h. prescription;
 - i. use;
 - j. disposal and destruction;
 - k. post-marketing surveillance, inspections and monitoring;
 - l. pharmacovigilance?
6. Is the use of medicated feed (and/or water) containing antimicrobials for non veterinary medical purposes (such as growth promotion) prohibited or restricted?

Sources of international guidance: Medicated feed

WOAH *Terrestrial Animal Health Code* (2024): [Glossary](#) and Chapters [3.2](#), [3.4](#) and [6.10](#).

FAO/WHO *Codex Alimentarius*

[Code of Practice on Good Animal Feeding](#) (CXC 54-2004): sections 3, 5.6 and 6.3.3.

[Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance](#) (CXC 61-2005).

4.4 Animal health and production

Overview

In combination with good animal production practices, a robust animal health system can help countries to prevent the occurrence and spread of diseases (and also prevent the incidence and limit the severity of outbreaks), thereby reducing the need for antimicrobials. Animal health laws are intended to prevent the introduction of diseases and thereby minimize the need for further control. Nevertheless, in those instances when a disease does occur, animal health laws may also provide a country with appropriate tools for a response through emergency measures, containment and eradication actions.

Where are animal health and production regulated?

Animal health is often regulated in laws on animal health, animal disease control or biosecurity. Aquatic animal health is sometimes regulated in fisheries and/or aquaculture legislation. In rare cases, individual species or wildlife health might be regulated in stand-alone legislation, or wildlife legislation. Animal health may also be addressed in agricultural production laws, and possibly in import/export legislation. Finally, countries may develop separate legislation to cover individual aspects of animal health and production – such as animal identification and traceability, farm registration, animal welfare or animal genetic resources. Slaughterhouse and meat inspection is often regulated in self-standing legislation, and game and hunting legislation may also include provisions for post-mortem inspections of game.

General elements for animal health and production legislation

Scope

The scope of animal health laws should include live animals (terrestrial and aquatic), animal health hazards in products of animal origin (including byproducts), animal genetic material, biological products and pathological material, as well as vectors and fomites. How these terms are defined in the legislation affects the scope of coverage; this in turn implies what actions may be taken, who can take the action, and which commodities are covered. Both *Terrestrial Code* and *Aquatic Code* glossaries define key terms that may be used to guide national legislation and harmonize it with international standards.

Institutional framework

Animal health laws should provide for a chain of command with clear delineation of the responsibilities of various authorities involved in disease control and trade from the central level to field level. This is particularly useful in covering AMR-relevant matters. Where more than one competent authorities are involved, a reliable system of coordination and cooperation should be in place, including clarifying the role of each authority (*Terrestrial Code*, Article 3.4.5).

Competent authorities should be given the legal power to: order disinfection, disinfestation or disease control measures; set up disease surveillance programmes (see below), and apply specific risk-based sanitary measures – such as seizure or destruction of commodities, suspension or closure of facilities, or parts of activities at a facility.

Laboratory infrastructure is also very important for AMR surveillance and the latter may utilize the laboratory infrastructure in place for animal diseases. According to the *Terrestrial Code* (Article 3.4.7), legislation should make provision for the functioning and quality requirements for: 1) reference laboratories; 2) laboratories for the analysis of official samples, and 3) laboratories that conduct safety and quality control testing.

Disease surveillance and early warning systems

Disease surveillance provisions provide the competent authority with a legal basis for the development and implementation of monitoring and control programmes. Legislation should allow the competent authority to develop a list of “notifiable” (sometimes referred to as “listed”) diseases, approve import requirements, and declare the disease status of an area. It should also allow for the collection, transmission, dissemination and use of epidemiological data (*Terrestrial Code*, Article 3.4.9). Chapter 1.4 in both *Terrestrial Code* and *Aquatic Code* sets out standards for disease surveillance systems. Legislation should also include a general duty on animal owners and veterinarians/authorized animal health professionals to report notifiable diseases.

Legislation should allow for measures to be taken to address all identified risks to human or animal health (*Terrestrial Code*, Article 3.4.9). Having detected a disease, an inspector should have the legal power to order the taking of measures to contain and eradicate the disease, such as prohibiting movement of the item or animal, prescribing certain treatments, or destroying the item or animal. Where the situation has been elevated to a disease outbreak or animal health emergency by the competent authority, legislation should give this authority or the responsible minister the power to declare an emergency. Legislation should require the establishment of an emergency response plan. During emergencies, the measures imposed may be stronger and more restrictive, but should be proportionate, technically justified and time-bound.

Import control

Legislation should prohibit the import (or the transit within the territory) of animal commodities that do not meet the requirements set by the law.

Animal health professions

Legislation should specify who can provide veterinary services – e.g. by establishing educational and qualification requirements for a person to be called a veterinarian, a VPP, an aquatic animal health professional, or other. One way of maintaining regulatory control over these categories is by establishing a licensing or registration scheme by a government or a self-regulatory body (e.g. a veterinary statutory body). Additionally, legislation should clearly establish the different kinds of veterinary services that the different categories can provide.

Animal welfare

Neglect of animal needs for appropriate feed, water, shelter and other aspects of care leads to increased risk of disease, infections and injury, which in turn requires increased use of antimicrobials. Specific welfare rules in legislation may cover, *inter alia*, animal housing, husbandry, transportation or slaughter. The law should stipulate that any person who owns, cares for, handles, uses, transports or sells any animal should be responsible for ensuring that its welfare needs are met.

Legislation should contain, at a minimum, a legal definition of “animal cruelty” as an offence, and provisions for direct intervention by the competent authority in the case of cruelty or neglect (*Terrestrial Code*, Article 3.4.10).

Waste management

As will also be discussed in Chapter 7 of this Tool, which deals with AMR and the environment, legislation can place requirements on animal waste management and introduce restrictions on the sale and use of animal waste, bedding and other materials as fertilizers, as these can be vectors for introducing antimicrobial-resistant pathogens into the environment.

Questions on animal health and production legislation

Scope

1. Where are animal health and production regulated?
2. Does legislation cover all animals, including:
 - a. livestock;
 - b. pets;
 - c. wild animals;
 - d. aquatic animals?
3. Are the definitions (such as “animal”) in legislation in line with those of both the *Terrestrial Code* and *Aquatic Code* glossaries?

Institutional framework

4. Is there a single national authority competent for animal health matters?
5. Does legislation recognize the veterinary authority has sufficient powers to guarantee a chain of command that ensures that the veterinary authority is able to adopt and implement sanitary measures across the entire territory of the country?

6. Does legislation give the competent authority the power to approve and implement animal health sanitary measures such as disease surveillance, disease-testing, movement control, or seizure and disposal of animals?
7. Does legislation give the competent authority the legal power to monitor and enforce compliance with veterinary legislation?

Disease surveillance and early warning system

8. Does legislation require the development of a list of notifiable/listed diseases by the competent authority?
9. Does legislation mandate all relevant actors (veterinarians/authorized animal health professionals, animal owners and others) to report suspected or verified cases of notifiable diseases?
10. Does legislation require the development of an emergency response plan or disease-specific response plans by the competent authority?
11. Does the competent authority or the responsible minister have the legal power to declare an animal health emergency?

Import control

12. Does legislation prohibit the import or transit of animal commodities that do not meet the requirements set by the law?

Animal health professions

13. Is there legislation on animal health professions that establishes the qualifications necessary to be:
 - a. a veterinarian;
 - b. a veterinary paraprofessional;
 - c. an aquatic animal health professional?
14. Does legislation require that these categories be licensed/registered by a government or self-regulatory body (e.g. a veterinary statutory body)?

Animal welfare

15. Does legislation identify the competent authority for animal welfare?
16. Do welfare provisions cover:
 - a. animal housing;
 - b. draught animals;
 - c. transportation;
 - d. stunning and slaughter;
 - e. any specific species or production systems (e.g. poultry)? Please specify.

Waste management

17. Does legislation require animal producers to ensure sound management of wastes (e.g. with biological and chemical residues)?
18. Does legislation impose restrictions in the use (e.g. as fertilizers) of manure or bedding from animals treated with antimicrobials?

Sources of international guidance: Animal health and production

WOAH *Terrestrial Animal Health Code* (2024): [Glossary](#) and Chapters [1.4](#), [3.4](#), [4.3](#), [6.10](#) and [6.11](#); and sections [2](#), [5](#) and [7](#).

WOAH *Aquatic Animal Health Code* (2024): [Glossary](#) and Chapters [1.4](#), [6.2](#) and [6.5](#); and sections [2](#), [5](#) and [7](#).

FAO/WHO *Codex Alimentarius Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance* (CXC 61-2005): sections 4, 5.1 and 5.5.

WTO *Agreement on Sanitary and Phytosanitary Measures* (SPS Agreement) (1995).

WOAH/FAO *Guide to Good Farming Practices for Animal Production Food Safety* (2010).

Chapter 5

Pesticide management



5.1 Relevance of pesticide management for addressing AMR

Overview

Pesticides are defined as “any substance, or mixture of substances of chemical or biological ingredients intended for repelling, destroying or controlling any pest, or regulating plant growth” (International Code of Conduct on Pesticide Management [ICCPM], Article 2). This broad definition includes antimicrobials and substances with antimicrobial effects. This definition encompasses pesticides used for crop protection, pesticides used in the veterinary sector and pesticides used for public health.

Where are pesticides regulated?

Pesticides are commonly regulated under specific pesticide legislation. Pesticides may also be regulated under general agricultural legislation, or under general plant protection laws that also include pesticide management. In addition, pesticides may be regulated under public health codes or in public health legislation (for household pesticides and pest control treatments), as well as in legislation on noxious substances and in legislation for specific vector or disease control. Pesticides might also be regulated under general chemicals legislation. Veterinary pesticides could be included in veterinary legislation.

Certain stages of the pesticide management lifecycle may be governed by the following: industrial products or general manufacturing laws; business licensing laws; environmental protection laws; advertising laws; consumer protection and product safety laws; occupational safety or labour laws; national statistics laws; waste disposal laws and hazardous waste laws. Finally, different aspects of pesticide production, use and disposal (including the collection of pesticide waste) might be addressed in general environmental legislation, pollution control laws or water laws.

5.2 General elements for a pesticides legal framework

Pesticide legislation should regulate all types of pesticides together and address all stages of the pesticide management lifecycle. Such a “cradle-to-grave” approach includes production (manufacture and formulation), registration, import, distribution, sale, supply, transport, storage, handling, application and disposal of pesticides and their containers (ICCPM, Article 2).

Pesticide legislation should designate the competent authority with ultimate responsibility for pesticide management in the country. This could be the ministry responsible for agriculture, for health or for the environment or, alternatively, this may be a separate body (*Guidance on pesticide legislation*, section 4.2). Among its responsibilities, the competent authority should coordinate all aspects of the pesticide lifecycle and cooperate with public and private stakeholders for such purposes.

Questions on general elements

1. Does the country have legislation on pesticides?
2. Does the scope of pesticides legislation include, in addition to pesticides for plants, those to be used on animals and for public health?
3. Does the pesticide legislation cover all the stages of the lifecycle (including disposal)?
4. Does the legislation:
 - a. identify the competent authority for pesticides management;
 - b. require the competent authority to coordinate or collaborate with other authorities in charge of human health, animal health and the environment?

5.3 Pesticide registration

Legislation should require that any pesticide that is distributed and used in the country should be registered by the competent authority. Legislation may outline data requirements for registration applications. Typically, both data requirements for dossiers and criteria that guide decisions on registration are designed to support assessments by the competent authority relating to the impacts of the pesticide on human health, animal health and the environment. Also, legislation should include decision-making criteria to enhance transparency in decision-making and avoid disputes with the applicant (*Guidance on pesticide legislation*, section 4.3.3).

Provisions on registration may also restrict or prohibit the use of antimicrobials featured on the WHO *List of Medically Important Antimicrobials* – previously known as the WHO *List of Critically Important Antimicrobials for Human Medicine*. Registration may thus restrict these antimicrobials for emergency use only (and in addition, strict regulatory control on their use may be imposed). Registration may also include specific restrictions or conditions in relation to the product, including on its handling and application.

Pesticide laws may establish a pesticide registration body, usually a board or another entity, to decide on pesticide registration. This pesticide registration body can integrate expertise from national agencies involved in different aspects of the pesticide management lifecycle, to ensure broad representation of the disciplines relevant for risk assessment. Such registration bodies are thus well-placed to examine any human-animal-environmental concerns, such as AMR.

Questions on the registration of pesticides

1. Is registration a requirement under law for the manufacture, import, distribution, sale and use of a pesticide?
2. Are there specific restrictions or prohibitions (including lists of banned or restricted pesticides) relating to which types of pesticides can be registered?
3. Does legislation establish or refer to data requirements for applications or decision-making criteria for pesticides registration that include assessment or consideration of the impacts on human health, animal health and the environment? Is there a pesticide registration body that includes representatives from human health, environment and agriculture?
4. Does legislation allow the registration authority to establish specific restrictions or conditions of use in order to register a pesticide?

5.4 Licensing

Licensing allows a government to maintain oversight on the facilities (location, design, processes, etc.) and the persons (i.e. their skills or experience) for production or manufacture, import, use and sale of (different categories of) pesticides.

Legislation should establish which pesticide-related activities (manufacture, formulation, sale, transportation, import, packaging or re-packaging or special applications, disposal) require a licence. Laws should require licence-holders (licensees) to comply with the conditions of their licence as well as with the legislation. An inspection system can be used to ensure compliance with requirements.

Questions on licensing

1. Does legislation require a licence for conducting the main activities related to pesticides during their lifecycle (manufacture, sale, specialized applications [e.g. aerial fumigation], import, disposal)?
2. Does the framework for licensing impose on the licensee the duty to keep records and report them to the pesticide authority?
3. Does legislation establish an inspection scheme to ensure compliance of licensees with conditions of their licences and requirements of the law?

5.5 Labelling

The primary purpose of labelling is to provide all necessary information needed for correct storage, handling and use of a pesticide.

The registration authority evaluates label exemplars during the registration process. Legislation should prohibit the sale of pesticides that do not bear the approved label.

Question on labelling

1. Does legislation prohibit the sale of pesticides that do not bear the approved label?

5.6 Disposal

Waste management during manufacturing and environmental dispersal resulting from the use of pesticides is addressed in Chapter 7 of this Tool. It is necessary that legislation clearly identifies the authority responsible for ensuring proper disposal of pesticides and pesticide wastes, including containers. Different laws may ascribe a mandate for the disposal of waste to different entities – most commonly to authorities responsible for agriculture, chemicals, pesticides or the environment. As it is possible that the legal framework has assigned authority to more than one entity, there should be a mechanism for cooperation or collaboration in place which should be overseen by the entity with ultimate responsibility for pesticides. Legislation may also impose obligations on sellers to receive back unused, obsolete pesticides or empty pesticide containers as part of a collection scheme.

Questions on disposal

1. Which entity is responsible for regulating the disposal of pesticide waste? If this entity is separate from the competent authority for pesticides management, is there a mechanism for cooperation or collaboration in place?
2. Are there requirements for the management and disposal of pesticide waste, including containers and unused or obsolete pesticides?

5.7 Data collection and exchange, and related activities

Collection of data on pesticides – including incident reporting, hazard identification and usage trends – is critical for the identifying and quantifying the actual risks of use. Data collection can inform policy decisions on the types of pests or diseases that necessitate antimicrobial therapy (and the appropriate product to be used). The collected data may also be sent to broader national surveillance systems that monitor antimicrobial use in other sectors (as well as global data collection).

The ICCPM recommends the use of all possible means to collect reliable data, to record statistics on environmental contamination and adverse effects and to report specific pesticide-related incidents. Legislation may assign responsibility for these monitoring and data collection functions to the competent authority for pesticide management. In this way, additional data collection and reporting obligations for antimicrobial pesticides, and pesticides with antimicrobial effects, may be imposed and reported or transmitted to the relevant AMR focal point or institution. Consequently, any provisions that refer to data exchange or coordination on data collection may be useful.

Question on data collection and exchange

1. Does the legislation assign a mandate to the competent authority for:
 - a. data collection;
 - b. data exchange with other authorities?

FAO/WHO Key international standards and references

FAO/WHO. [International Code of Conduct on Pesticide Management](#) (2014).

FAO/WHO. [Guidance on pesticide legislation](#), Second edition (2020).

FAO/WHO. [Guidance on good labelling practice for pesticides](#) (2017).

FAO/WOAH/WHO. [Monitoring and evaluation of the global action plan on antimicrobial resistance: framework and recommended indicators](#) (2019).

Reference for Chapter 5

Sundin, G.W., & Wang, N., 2018. Antibiotic resistance in plant-pathogenic bacteria. *Annu Rev Phytopathol.* 2018;56:161–80. (<https://pubmed.ncbi.nlm.nih.gov/29856934/>, accessed 27 July 2023).

Chapter 6

Plant health



6.1 Relevance of plant health frameworks for addressing AMR

Overview

For the purposes of this Tool, plant health refers to “the discipline that utilises official or legislative approaches to prevent pests and disease-causing organisms to spread into endangered areas, especially through human interaction such as international trade” (CPM, 2016). The purpose of legislation on plant health is to prevent the introduction and spread of pests and to protect plant resources (including cultivated, wild and aquatic plants) through the implementation of phytosanitary measures. This Chapter highlights select key legal elements for regulating plant health matters.

Where are plant health matters regulated?

Plant health matters are often regulated in plant health, plant protection or phytosanitary laws. Plant health may also be addressed under broader biosecurity legislation, or general agriculture legislation.

6.2 Scope of laws

Plant health laws govern all plant pests (including weeds and invasive alien species, biological control agents and living modified organisms). The scope of plant health laws should include plants, plant products and other regulated articles (including soil, wood packaging materials and conveyances).

Questions on scope

1. Is there a law on plant health aimed at protecting plants from risks arising from plant pests?
2. Does the phytosanitary legislation cover all plants (cultivated and wild plants, trees and forests as well as aquatic plants)?

6.3 Institutional arrangements for plant health

The IPPC requires each contracting party to establish a National Plant Protection Organization (NPPO), define its structure and be assigned the following functions (IPPC, Article IV), among others, to be included in the phytosanitary laws:

- (i) conducting pest risk analysis;
- (ii) conducting surveillance for plant pests on growing plants, including both areas under cultivation (e.g. fields, plantations, nurseries, gardens, greenhouses and laboratories) and wild flora, and on plants and plant products in storage or in transportation;
- (iii) inspection during import and export with the objective of preventing the introduction and spread of pests;
- (iv) issuing phytosanitary certificates for exported consignments;

- (v) protection of endangered areas;
- (vi) designation and maintenance of pest-free areas and areas of low pest prevalence; and
- (vii) responding to pest outbreaks and phytosanitary emergencies.

Questions on institutional arrangements

1. Does legislation establish a NPPO or responsible body for plant protection?
2. Are any responsibilities that should be assigned to the NPPO (see above) missing in the legal framework?
 - a. Is the NPPO or responsible body for plant protection mandated to regulate and control plant pests both internally (in cultivated plants and wild flora) and in international trade?
3. Does the NPPO have the power to adopt and implement phytosanitary measures?

6.4 Import

Plant health legislation should establish that plants, plant products or other regulated articles should not be imported unless they meet the country's phytosanitary import requirements set by law.

Question on import

1. Does legislation prohibit import of consignments that do not meet the phytosanitary import requirements established by law?

6.5 Export

The IPPC requires that each contracting party makes arrangements for phytosanitary certification, with the objective of ensuring that exported plants, plant products and other regulated articles are in conformity with the phytosanitary import requirements of the importing country (Article V(1), IPPC; ISPM 7).

Question on export

1. Does legislation require the issuance of phytosanitary certificates where export consignments meet the phytosanitary requirements of importing countries?

Key international standards and references

FAO. [International Plant Protection Convention](#) (IPPC) (1999).

FAO. [International Standards for Phytosanitary Measures](#) (ISPMs).

References for Chapter 6

Document CPM 2016/34. Report on the activities relating to the International Year of Plant Health in 2020 (IYPH 2020) – Scope, objectives and structures for the International Year of Plant Health. Commission on Phytosanitary Measures, eleventh session, Rome, 4–8 April 2016 (https://assets.ippc.int/static/media/files/publication/en/2016/03/34_CPM_April_2016-IYPH_planning-2016-03-10.pdf, accessed 27 July 2023).

Document CPM 2019/INF/12. Antimicrobial resistance (AMR) – Antimicrobial resistance (AMR) in relation to plant health aspects. Commission on Phytosanitary Measures, fourteenth session, Rome, 1–5 April 2019 (https://www.ippc.int/static/media/files/publication/en/2019/02/INF_12_CPM_2019_AMR-2019-02-20.pdf, accessed 27 July 2023).

Chapter 7

The environment



7.1 Environmental dimensions of AMR

Overview

There is growing evidence that the environment plays a key role in the development, transmission and spread of AMR (UNEP, 2023). AMR can develop and spread in the environment through emissions of antimicrobials and their residues and metabolites, as well as through the release of antimicrobial-resistant microorganisms and the transfer/mobility of resistant genes (UNEP, 2023). These various sources are collectively referred to in this chapter as AMR-relevant pollutants.

The key economic sectors and their value chains contributing to environmental dimensions of AMR can be broadly classified as:

- (i) manufacturing of pharmaceuticals, active pharmaceutical ingredients and other chemicals, used for a variety of purposes (human medicines, VMPs, pesticides, etc.);
- (ii) agriculture, including antimicrobial use in terrestrial and aquatic animal production, and crop production;
- (iii) health care in hospitals, clinics, community health-care facilities, laboratories and other medical facilities where antimicrobials may be used, as well as pharmacies (UNEP, 2023).

Another key pollution source comes from poor sanitation, sewage and community and municipal wastes (UNEP, 2023).

This section examines selected regulatory mechanisms and features that are commonly found in environmental and natural resources laws and that can be used to prevent and address environmental dimensions of AMR. Chapters 2–6 of this Tool address regulatory controls over the spectrum of activities and facilities related to antimicrobials across their entire lifecycle. It is underscored that interventions upstream have significant effects on the downstream discharge and release of AMR-relevant pollutants into the environment.

Where are the environmental dimensions of AMR regulated?

In view of the many environmental dimensions of AMR introduced in the preceding sections, provisions relevant to this analysis may be found across a broad range of environmental laws. These include: legislation governing specific environmental media – such as water management legislation or soil legislation – as well as their corresponding quality standards; general environment-related legislation; pollution prevention and control legislation; chemicals management legislation; legislation on natural resources, including laws on biodiversity, climate change, wildlife and forestry; protected areas legislation; agriculture legislation for all types of production systems; water infrastructure, sewage, sanitation and wastewater legislation; pharmaceuticals legislation; procurement legislation; business authorization legislation, and waste management and disposal legislation.

Relevant provisions for waste management can be found in general waste management legislation, municipality legislation or landfill legislation. Waste laws may be established for waste in general, or specifically for medical waste.

Waste management may also be addressed in legislation on the environment, business authorization, soil, noxious or polluting activities, agriculture, health, pharmaceuticals, pesticides and feed. Finally, there could also be relevant elements in legislation on sustainability, circular economy, recycling and waste reduction.

7.2 Institutional frameworks for environmental management

7.2.1 Institutional arrangements

Key elements

Most jurisdictions have a dedicated authority for environmental matters. As many relevant environmental management processes are the primary responsibility of the competent authority for the environment, institutional coordination is important in order adequately to address the multisectoral dimensions of AMR collaboratively with the competent authorities for human health and animal health. Coordination is also important for effective integrated monitoring and surveillance – a critical element of national responses to AMR – across sectors and levels of government.

Legislation should identify the lead agency for the regulation of wastewater, the responsibilities of other agencies (health, environment, agriculture) and also the roles of entities at local level.

Questions

1. Does the legal framework contain any provision for cooperation or coordination between the environmental agency and the authorities responsible for human health and agriculture (including terrestrial and aquatic animal health, crop production, etc.)?
2. Is environmental management split between the central and the decentralised (local/provincial levels)? If yes, please describe arrangements or mechanisms for coordination for:
 - a. water management;
 - b. wastewater? If so, please name the entities and state their roles.

7.2.2 Standard-setting and enforcement

Key elements

Water quality and soil quality standards, coupled with provisions on sampling and testing that are part of broader environmental monitoring and surveillance systems, offer an entry point in the framework into which AMR-specific parameters can be introduced. Legislation should establish the entity responsible for setting standards and targets (and the process for doing so), and the entity responsible for enforcement, including inspections and monitoring.

Questions

1. Does legislation contain general/overarching provisions to protect against or to prevent the pollution of:
 - a. water resources, including groundwater;
 - b. soil?
2. Does the legislation establish the necessary powers and responsibilities for the competent authority to carry out surveillance and monitoring of:
 - a. water resources, including groundwater;
 - b. soil?
3. Is there legislation that provides for the establishment of:
 - a. water quality standards;
 - b. soil quality standards;
 - c. effluent/discharge/emission standards?

7.3 Scope of application of pollution and waste legislation

Key elements

Scope of pollution laws

Legislation may establish a definition of pollution (which is often broad), and may also specify (or set up a mechanism to identify) what substances are considered pollutants. The definition of pollutants may allow for inclusion of AMR-relevant biological and chemical pollutants. Legislation will typically identify the activities or facilities that may generate pollution. It is therefore important to determine whether the activities or facilities that may generate point-source pollution canvassed in the Overview in section 7.1 would be included in the relevant law.

Scope of waste laws

The legal framework on waste management usually differentiates requirements based on how the jurisdiction categorizes its waste. Stipulations may vary for the different types and classifications of waste based on the risks (e.g. hazardous waste) and source (industrial, agricultural, etc.). The different types of waste are often defined in legislation and thus it is important to assess whether waste from various sources of AMR-relevant pollutants would fall under any of these definitions.

Questions

1. Does legislation define or regulate pollution or pollutant in a manner that is broad enough to include antimicrobials and antimicrobial residues, metabolites and resistant microorganisms or genes?
2. Does legislation define waste in a manner that allows for the inclusion of:
 - a. antimicrobial leftovers or obsolete antimicrobials;
 - b. antimicrobials packaging or containers?

7.4 Addressing pollution from economic sector activities

This section explores mechanisms to address the pollution generated by economic sector activities relevant for AMR including manufacturing, agriculture and health care. The manufacture of pharmaceuticals, active pharmaceutical ingredients and other chemicals can generate AMR-relevant pollution. Livestock production, both terrestrial and aquatic, is also a significant source of pollution due to antimicrobial use and overuse. Antimicrobials may spread in the environment both from and to agricultural (including crop) production sites. The health sector, including health-care services, laboratories and pharmacies, is another significant source of AMR-relevant pollution via disposal of waste and pharmaceutical waste.

7.4.1 General mechanisms to prevent and address pollution

Key elements

Financial incentives to prevent pollution

Another way to target pollution is to discourage it. Legislation may establish financial tools, including economic incentives for promoting green chemistry, the adoption of cleaner technologies and improved facilities/infrastructure to reduce point source pollution.

Pollutant release and transfer registers

Legislation may establish pollutant release and transfer registers. Such registers are publicly accessible databases of chemicals or other pollutants released to environmental media and transferred off-site for treatment. These registers may eventually incorporate AMR-relevant data.

Questions

Financial and other incentives

1. Does legislation establish:
 - a. financial or other incentives that specifically help minimize pollution for e.g. manufacturing technologies or facilities;
 - b. procurement rules or agricultural subsidy rules that favour products produced in compliance with prescribed environmental standards?

Pollutant release and transfer registers

2. Does legislation establish national pollutant release and transfer registers?

7.4.2 Targeting pollution specifically from economic sector activities

Key elements

Geographic restrictions and prohibitions

Legislation may expressly prohibit certain manufacturing, agricultural or other prescribed activities in certain areas, including near bodies of water, schools, or densely populated areas or protected zones.

Conditions of licence to operate: environmental impact assessment, audit and monitoring, and waste management

The issuance of a licence to operate manufacturing or large-scale facilities is often accompanied by specific conditions. Legislation may establish that an environmental impact assessment (EIA), or similar environmental risk assessment processes, must be submitted to and approved by the competent authority for environmental matters as a condition for a licence or permit to operate. As a condition of a licence, legislation may require operators to conduct environmental audits (self-assessment or via a third party), establish waste management plans and monitor environmental compliance and impact.

Record-keeping and reporting measures may be imposed by law to track the movement of waste until its safe treatment or disposal.

Waste disposal

A general rule is that waste should be prevented, and if generated, should be treated before release into any environmental media. Different types of waste require different methods of disposal. Legislation may set out provisions to reduce, eliminate or otherwise regulate different types of waste.

Municipal solid-waste landfills and open dumps may serve as ideal environments for the development and transmission of AMR. Accordingly, legislation addressing the management of solid-waste landfills may contain relevant provisions to reduce the spread of AMR.

Requirements for operations that treat and manage waste

Legislation often requires permits to be issued for those who carry out waste treatment, whether professionally or as part of the manufacturing of pharmaceuticals. The competent authority should keep a register of establishments that collect, transport or treat waste (including sewage).

Wastewater discharge

Wastewater discharge from agricultural, industrial, household and other sources may contain AMR-relevant pollutants. Legislation may either completely prohibit the release of wastewater into various environmental media or may allow it subject to issuance of a permit. Discharge authorizations are usually accompanied by requirements for self-assessment and reporting, and an EIA.

Questions

Geographical restrictions and prohibitions

1. Is there legislation that places restrictions on the types of activities (industrial, agricultural) that can be carried out in or near water sources, or that otherwise restricts activities to certain sites?

Conditions of licenses to operate

2. Does the requirement of an EIA apply to activities that manufacture, use or dispose of antimicrobials – such as farms (all types of production), feed mills, pharmaceutical companies, hospitals and clinics, etc.?
3. Does legislation require licensees who manufacture antimicrobials (veterinary medicinal products, human medicines, antimicrobial pesticides) to:
 - a. submit to periodic inspections for environmental compliance;
 - b. carry out environmental auditing;
 - c. ensure that emergency measures are in place for exceptional situations such as leakages, etc.;
 - d. comply with waste/effluent discharge standards;
 - e. comply with record-keeping and reporting measures, including to track the movement of the waste through its safe treatment and disposal;
 - f. adopt waste management plans?

Waste disposal

4. Does legislation contain provisions that require the treatment of waste before releasing it?

Requirements for operations that treat and manage waste

5. Does legislation require permits for those who carry out waste treatment?
6. Does the law impose certain duties of care on operators that transport, handle and/or treat waste?
7. Does legislation have provisions regulating environmental impacts of municipal solid waste landfills?

Wastewater discharge

8. Does legislation require authorizations/permits to be issued for wastewater discharges?

7.4.3 Specific considerations for AMR-relevant sectors

Key elements

Manufacture

Legislation may establish specific obligations along the value chain for manufacturers and others to take various responsibilities under a lifecycle approach. Legislation may require a facility that generates and disposes of its waste to be issued with a waste or effluent discharge permit.

Agriculture

Legislation in the agriculture sector targets safe disposal of VMPs, antimicrobial pesticides and medicated feed (see Chapters 4 and 5 of this Tool). Water quality standards aim to guarantee safe water inputs for crop, livestock and aquaculture facilities. Legislation may contain provisions that specifically target the use of antimicrobials in aquaculture establishments in open water or in flow-through systems.

Health care

Legislation may target antimicrobials emissions from unused and expired pharmaceuticals originating from health-care facilities through the treatment and management of waste (see various mechanisms under section 7.4.2 as well as section 2.4.1. of Chapter 2 on antimicrobial stewardship relating to health-care facilities). Legislation may also impose specific waste collection schemes, including waste medicines collected by pharmacies and hospitals or take-back schemes in shops.

Questions

Waste from manufacturing

1. Does the legislation require the issuance of discharge permits for the release of waste from manufacturing of antimicrobials?

Agriculture

2. Is there legislation on the use of antimicrobials in aquaculture establishments in open water or in flow-through systems?

Health care

3. Does legislation impose any collection schemes for waste that may include antimicrobial waste (leftovers, containers) – e.g. by pharmacies, hospitals?

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