



# Antimicrobial Resistance: A Legal and Public Health Perspective

Nwakoby, I. P.<sup>1\*</sup>, Iheukwumere, I. H.<sup>2\*</sup>, Iheukwumere, C. M.<sup>3</sup>, Nwakoby, N. E.<sup>2</sup>,  
Idigo, M. A.<sup>4</sup> and Ike, V. E.<sup>5</sup>

<sup>1</sup>Department of Private and Public Law, Faculty of Law, Chukwuemeka Odumegwu Ojukwu University, Anambra State, Nigeria.

<sup>2</sup>Department of Microbiology, Faculty of Natural Sciences, Chukwuemeka Odumegwu Ojukwu University, Anambra State, Nigeria.

<sup>3</sup>Department of Applied Microbiology & Brewing, Faculty of Biosciences, Nnamdi Azikiwe University, Awka, Anambra State, Nigeria.

<sup>4</sup>Department of Biological Sciences, Faculty of Natural Science, Chukwuemeka Odumegwu Ojukwu University, Anambra State, Nigeria.

<sup>5</sup>Department of Microbiology, University of Agriculture and Environmental Sciences, Umuagwo, Imo State, Nigeria.

\*Corresponding author e-mail address: [ip.nwakoby@coou.edu.ng](mailto:ip.nwakoby@coou.edu.ng) / [ik.ihewkumere@coou.edu.ng](mailto:ik.ihewkumere@coou.edu.ng)

Abstract	Article History
<p>Antimicrobial resistance (AMR) represents one of the most severe and complex global public health crises of the 21st century. It threatens the very foundation of modern medicine, rendering standard treatments ineffective and leading to increased morbidity, mortality, and healthcare costs. This review provides a comprehensive analysis of AMR through the dual lenses of public health and law. It begins by outlining the scale and drivers of the AMR crisis from a public health standpoint, including its clinical and economic impacts. The core of the review examines the existing and proposed legal frameworks at national and international levels designed to combat AMR. This includes analysis of pharmaceutical regulation, agricultural use of antimicrobials, infection prevention and control laws, and incentives for research and development (R&amp;D) of novel antimicrobials. The review concludes that while significant scientific and medical efforts are underway, a robust, coordinated, and legally enforceable global response is critically lacking. Effective mitigation of AMR requires a "One Health" approach, integrating human, animal, and environmental health, supported by strong legal instruments that translate policy into actionable and accountable measures.</p> <p><b>Keywords:</b> Antimicrobial Resistance, Public Health Law, One Health, Antibiotic Stewardship, Global Health Governance, Pharmaceutical Policy, Infection Control.</p>	<p>Received: 26 Sept 2025 Accepted: 15 Oct 2025 Published: 19 Oct 2025</p>  <p>Scan QR code to view*</p> <p>License: CC BY 4.0*</p>  <p>Open Access article.</p>
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## 1.0 INTRODUCTION: THE SILENT PANDEMIC

Antimicrobial resistance (AMR) occurs when bacteria, viruses, fungi, and parasites change over time and no longer respond to medicines, making infections harder to treat and increasing the risk of disease spread, severe illness, and death (WHO, 2021a; Iheukwumere *et al.*, 2025a). The phenomenon is a natural evolutionary process, but it has been drastically accelerated by human activity, including the misuse and overuse of antimicrobials in human health, animal husbandry, and agriculture. The World Health Organization (WHO) has declared AMR one of the top 10 global public health threats facing humanity (WHO, 2021a). A seminal review on the global burden of AMR estimated that in 2019, bacterial AMR was directly responsible for approximately 1.27 million deaths and was associated with nearly 4.95 million deaths globally (Antimicrobial Resistance Collaborators, 2022; Iheukwumere *et al.*, 2025b; Iheukwumere *et al.*, 2025c). Without urgent and

coordinated action, this number is projected to rise to 10 million annual deaths by 2050, with a cumulative economic cost of \$100 trillion to the global economy (O'Neill, 2016). These staggering figures underscore that AMR is not a future threat but a present reality, demanding an immediate and multifaceted response.

This review argues that while the public health community has successfully diagnosed the problem and proposed technical solutions (e.g., stewardship, surveillance), the translation of these solutions into effective, sustainable action is fundamentally a legal and governance challenge. Law acts as a critical tool to structure responses, allocate resources, enforce standards, and ensure accountability. This paper will explore the public health dimensions of AMR before delving into the essential legal frameworks required to contain this crisis.

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## 2.0 PUBLIC HEALTH PERSPECTIVE: UNDERSTANDING THE SCALE AND DRIVERS OF AMR

The public health perspective on AMR involves understanding its epidemiology, its drivers, and the strategies required for its containment through a population-level lens.

### 2.1 Clinical and Economic Impact

The rise of multidrug-resistant organisms (MDROs), such as methicillin-resistant *Staphylococcus aureus* (MRSA), extensively drug-resistant *Mycobacterium tuberculosis* (XDR-TB), and carbapenem-resistant Enterobacteriaceae (CRE), has created scenarios where previously treatable infections become life-threatening (Iheukwumere *et al.*, 2025d; Iheukwumere *et al.*, 2025e). This leads to:

- ✓ Increased Mortality and Morbidity: Longer durations of illness, higher risk of complications, and increased case-fatality rates.
- ✓ Prolonged Hospital Stays: Patients with resistant infections often require longer hospitalization, increasing their risk of hospital-acquired infections and placing a greater burden on healthcare systems.
- ✓ Higher Healthcare Costs: Costs escalate due to the need for more expensive second- and third-line drugs, extended hospital stays, and the requirement for more complex diagnostic tests and isolation procedures (CDC, 2019).
- ✓ Threat to Modern Medicine: Many advanced medical procedures, including chemotherapy, organ transplantation, and major surgery (e.g., cesarean sections, hip replacements), rely on the ability to prevent and treat infections. Without effective antibiotics, these procedures become exponentially riskier.

### 2.2 Key Drivers of AMR

The drivers of AMR are multifaceted and interconnected across human, animal, and environmental sectors.

**Misuse in Human Health:** This includes the over-prescription of antibiotics by healthcare providers, often for viral infections where they are ineffective; patient demand for antibiotics; and failure to complete prescribed courses of treatment, which can allow resistant bacteria to survive and multiply (Ventola, 2015; Iheukwumere *et al.*, 2025f; Iheukwumere *et al.*, 2025g).

**Overuse in Agriculture and Aquaculture:** An estimated 70-80% of all medically important antibiotics in some countries are sold for use in animals, largely for growth promotion and disease prevention in crowded, unsanitary conditions (FDA, 2022). This practice creates a reservoir of resistant bacteria that can be transmitted to humans through food, direct contact with animals, or environmental contamination (Iheukwumere *et al.*, 2025h; Iheukwumere *et al.*, 2025i).

**Environmental Pollution:** Pharmaceutical manufacturing discharge and improper disposal of human and animal waste can release active antimicrobial ingredients and resistant bacteria into water and soil, further amplifying resistance in the environment (Larsson and Flach, 2022; Iheukwumere *et al.*, 2025j; Iheukwumere *et al.*, 2025k; Ekesiobi *et al.*, 2025).

**Paucity of New Antimicrobials:** The pipeline for new antibiotics is dry. From a commercial perspective, developing new antibiotics is financially unattractive for pharmaceutical companies. New antibiotics are typically used as a last resort and for short durations, limiting their profitability compared to drugs for chronic conditions. Consequently, many major pharmaceutical companies have abandoned antibiotic R and D (The Pew Charitable Trusts, 2022; Iheukwumere *et al.*, 2025l; Ekechukwu *et al.*, 2025a).

### 2.3 Core Public Health Strategies: The "One Health" Approach

Addressing these drivers requires a coordinated "One Health" approach that recognizes the interconnectedness of human, animal, and environmental health. Core public health strategies include:

**Surveillance:** Strengthening national and global systems to track resistance patterns and antimicrobial consumption in human and animal populations.

**Infection Prevention and Control (IPC):** Enhancing hygiene, sanitation, and vaccination rates to prevent infections from occurring in the first place, thereby reducing the need for antimicrobials (Ekechukwu *et al.*, 2025b; Ekechukwu *et al.*, 2025c).

**Antimicrobial Stewardship (AMS):** Promoting the responsible use of antimicrobials through guidelines, education, and monitoring to ensure the right drug, dose, and duration are selected.

**Public Awareness:** Educating the public, healthcare professionals, and policymakers about the threat of AMR and the importance of appropriate antimicrobial use.

While these strategies are widely endorsed by bodies like the WHO and the Centers for Disease Control and Prevention (CDC), their implementation is inconsistent and often voluntary. This is where law becomes an indispensable instrument to codify and enforce these public health goals.

### 3.0 The Legal Landscape: Frameworks to Combat AMR

Law provides the structure and authority to implement public health strategies. The legal response to AMR is fragmented, existing at international, regional, and national levels, and across various domains of law, including health law, agricultural law, environmental law, and intellectual property law.

#### 3.1 International Legal Frameworks

Currently, there is no binding international treaty dedicated solely to AMR. The response has been largely governed by soft law instruments—non-binding resolutions, guidelines, and action plans.

**The International Health Regulations (IHR 2005):** While primarily focused on acute public health events, the IHR mandate that countries develop core capacities for surveillance and response, which could be interpreted to include capacities for AMR surveillance (Gostin & Katz, 2016; Dim *et al.*, 2025a; Dim *et al.*, 2025b). However, the IHR are not specific to AMR and enforcement mechanisms are weak.

**World Health Organization (WHO) Global Action Plan (GAP) on AMR:** Adopted by the World Health Assembly in 2015, the GAP is the cornerstone of the global political response. It provides a non-binding framework for countries to develop their own National Action Plans (NAPs) based on five strategic objectives: (1) improve awareness and understanding; (2) strengthen surveillance and research; (3) reduce the incidence of infection; (4) optimize the use of antimicrobial medicines; and (5) ensure sustainable investment in new medicines and tools (WHO, 2015). While influential, its non-binding nature means implementation is voluntary and uneven.

**The Tripartite Collaboration:** The WHO, the World Organisation for Animal Health (WOAH, founded as OIE), and the Food and Agriculture Organization of the UN (FAO) have collaborated to promote a "One Health" approach. This collaboration has been crucial in aligning messaging but lacks legal authority to compel state action.

**Codex Alimentarius:** This joint FAO/WHO food standards program has developed guidelines on the responsible use of antimicrobials in food-producing animals, which can be referenced by countries in their national regulations (Codex Alimentarius, 2021; Dim *et al.*, 2025c; Ike *et al.*, 2025a).

The lack of a binding treaty is a significant gap in the global governance of AMR. Proposals for an international treaty on AMR have been put forward, which could include commitments on surveillance, regulation of antimicrobial use, and financing for R&D (Hoffman *et al.*, 2015; Ike *et al.*, 2025b; Ike *et al.*, 2025c). However, achieving consensus on such a treaty remains a formidable political challenge.

### 3.2 Regional Legal Frameworks

Regional bodies have begun to take more concrete legal steps, providing models for potential global action.

**European Union (EU):** The EU has one of the most advanced regulatory frameworks for AMR.

**Regulation on Veterinary Medicinal Products (2019/6):** This landmark regulation, which came into force in 2022, prohibits the prophylactic use of antibiotics in groups of animals (metaphylaxis) and bans the use of antibiotics for growth promotion. It also restricts the use of critically important antimicrobials for human medicine in animals (European Parliament and Council, 2019).

**One Health Network:** EU countries coordinate their actions on AMR through a network that uses a common strategic approach and monitors indicators of consumption and resistance.

**Other Regions:** Other regions, such as the African Union and ASEAN, have developed regional strategies, but these are largely policy-oriented rather than legally binding.

## 4.0 NATIONAL LEGAL FRAMEWORKS: A PATCHWORK OF APPROACHES

National laws are where international and regional guidelines are ultimately implemented. The strength of these laws varies dramatically from country to country.

### 4.1 Regulating Human Health Use

Laws governing the use of antimicrobials in human medicine typically focus on two areas: access and oversight.

**Prescription-Only Status:** A fundamental legal measure is to classify antibiotics as prescription-only medicines. However, enforcement is a major issue. In many low- and middle-income countries (LMICs), antibiotics are often available over-the-counter without a prescription due to weak regulatory enforcement, lack of access to healthcare, and economic incentives for pharmacies (Frost *et al.*, 2019). Laws must be coupled with strong regulatory capacity and enforcement mechanisms.

**Mandating Antimicrobial Stewardship Programs (ASPs):** Some high-income countries have begun to legally mandate ASPs in healthcare settings. For example, in the United States, the Centers for Medicare & Medicaid Services (CMS) Conditions of Participation require hospitals to have antibiotic stewardship programs as a condition for receiving federal reimbursement (CDC, 2019). This creates a powerful financial incentive for compliance. Other countries can enact similar legislation or regulations that require accredited hospitals to implement stewardship protocols.

### 4.2 Regulating Agricultural and Veterinary Use

Legal measures to curb non-human use are critical, as this sector accounts for a large proportion of global antibiotic consumption.

**Banning Growth Promotion:** Following the EU's lead, several countries have enacted bans on the use of antibiotics for growth promotion. For instance, the U.S. FDA's Guidance for Industry #213 implemented a voluntary plan to phase out the use of medically important antibiotics for growth promotion in food-producing animals, which was largely successful due to industry buy-in (FDA, 2022). However, a voluntary approach may be less effective in other contexts, and a legislative ban provides more durability and enforceability.

**Regulating Veterinary Prescriptions:** Laws that require veterinary oversight and prescriptions for antibiotics used in livestock are essential. These laws prevent the blanket prophylactic use of antibiotics and ensure they are used only for treating diagnosed diseases.

**Setting Maximum Residue Limits (MRLs):** Food safety laws typically include MRLs for antibiotic residues in food products like meat, milk, and eggs, which helps monitor and control improper use.

### 4.3 Regulating Environmental Discharge

This is an emerging and critically underdeveloped area of AMR law. While general environmental laws on industrial

wastewater discharge exist, they are rarely specific to pharmaceutical pollutants.

**Good Manufacturing Practices (GMP):** Regulations can require pharmaceutical manufacturers to implement waste treatment technologies to minimize the release of active antibiotic ingredients into the environment. Sweden, for example, has incorporated environmental risk assessments into its marketing authorization process for pharmaceuticals (Larsson and Flach, 2022).

**Wastewater Treatment Regulations:** Upgrading regulations to require municipal and agricultural wastewater treatment plants to implement technologies capable of removing pharmaceutical residues and resistant bacteria could significantly reduce environmental AMR load (Ike *et al.*, 2025d; Ike *et al.*, 2025e; Ugwu *et al.*, 2025a).

**4.4 Intellectual Property Law and Incentivizing Innovation**  
The market failure in antibiotic R and D requires legal and policy interventions to create new economic models.

**Push Incentives:** These are designed to lower the cost of R&D. They include direct government grants, tax credits for research expenses, and public-private partnerships. The U.S. Biomedical Advanced Research and Development Authority (BARDA) provides significant funding for late-stage antibiotic development (The Pew Charitable Trusts, 2022).

**Pull Incentives:** These are designed to create a viable market for successful new products. They guarantee a financial return upon achieving regulatory approval, de-linking profit from volume of sales. Key models include:

- ✓ **Market Entry Rewards (MERs):** Large, upfront monetary prizes for the development of a priority antibiotic.
- ✓ **Transferable Exclusivity Vouchers (TEVs):** Granting a voucher for an additional period of market exclusivity for a different, more profitable drug (e.g., a blockbuster cancer drug) to a company that brings a new antibiotic to market. This has been proposed in legislation like the PASTEUR Act in the U.S. (Outterson *et al.*, 2020).
- ✓ **Subscription Models:** Governments pay an annual subscription fee for access to a new antibiotic, regardless of volume used, guaranteeing the manufacturer a fixed income. The UK's NHS is piloting such a model (NICE, 2022).

Navigating intellectual property law is crucial. While patents are necessary to incentivize initial investment, pull mechanisms like MERs can work within or alongside the patent system to ensure both innovation and appropriate use.

## 5.0 CRITICAL ANALYSIS: GAPS AND CHALLENGES IN THE LEGAL RESPONSE

Despite the proliferation of action plans and some strong national laws, the overall legal response remains inadequate to the scale of the AMR threat.

### 5.1 The Governance Gap: Fragmentation and Soft Law

The primary weakness is the reliance on non-binding instruments at the international level. The WHO GAP, while

valuable, lacks enforcement mechanisms. There is no central authority to monitor compliance, assess the adequacy of National Action Plans, or hold countries accountable for inaction. This has resulted in a fragmented global response where progress is uneven, and the weakest links in the global health system can undermine the efforts of others (Røttingen & Gopinathan, 2020).

### 5.2 The Implementation Gap: Capacity and Enforcement

Even where strong laws exist, many countries, particularly LMICs, lack the technical capacity, financial resources, and regulatory infrastructure to enforce them. This is evident in the persistent over-the-counter sale of antibiotics and the unregulated use of antimicrobials in animals due to under-resourced inspectorates and veterinary services (Frost *et al.*, 2019). A law that cannot be enforced is merely a suggestion.

### 5.3 The Economic and Equity Gap

The high cost of developing and accessing new antibiotics creates a profound equity issue. Pull incentives like market entry rewards require significant public funding, raising questions about who will pay and how the resulting drugs will be made affordable and accessible globally. LMICs, which often bear the highest burden of resistant infections, may be priced out of new treatments. A global treaty could include provisions for a pooled fund for R&D and equitable access agreements, but this requires unprecedented international cooperation and financial commitment (Hoffman *et al.*, 2015).

### 5.4 The "One Health" Legal Gap

Laws are often siloed. Health ministries regulate human use, agriculture ministries regulate animal use, and environment ministries regulate pollution. There is a stark lack of legal frameworks that formally integrate these sectors and mandate cross-ministerial coordination. A truly effective "One Health" law would require these disparate agencies to share data, align strategies, and be jointly accountable for outcomes—a significant legal and administrative challenge.

## 6.0 CASE STUDIES IN LEGAL INTERVENTION

### 6.1 Success Story: The European Union's Comprehensive Approach

The EU demonstrates how a strong regional legal framework can drive progress. The combination of a ban on growth promoters, strict regulations on veterinary medicines, robust surveillance systems (e.g., the European Antimicrobial Resistance Surveillance Network - EARS-Net), and cross-border coordination has led to a significant reduction in antimicrobial consumption in animals and stabilized resistance rates in some human pathogens (ECDC, 2022). The key to success has been the use of binding regulations that apply uniformly across member states, creating a level playing field and preventing a "race to the bottom."

### 6.2 The Challenge: Over-the-Counter Sales in India

India has one of the highest rates of antibiotic consumption and resistance in the world. The country has a National Action Plan and laws that classify antibiotics as prescription-only. However, enforcement is extremely weak. Studies consistently show that antibiotics are widely available without a

prescription from pharmacies, driven by patient demand, lack of access to healthcare, and economic incentives for pharmacists (Frost *et al.*, 2019). This case highlights that without addressing the underlying drivers (e.g., healthcare access, pharmacist training, and economic incentives) and investing in enforcement capacity, laws alone are insufficient.

### 6.3 Innovation Experiment: The UK's Subscription Model

The UK is a pioneer in testing pull incentives. The National Health Service (NHS) has implemented a pilot project where it will pay manufacturers a fixed annual fee ("subscription") for access to two new antibiotics, ceftazidime-avibactam and cefiderocol, based on a health technology assessment of their value to the healthcare system, not on the volume used (NICE, 2022). This model aims to provide a predictable return for companies while delinking profit from sales volume, encouraging conservation. The results of this pilot will be closely watched as a model for other countries.

## 7.0 RECOMMENDATIONS FOR A ROBUST LEGAL AND PUBLIC HEALTH FRAMEWORK

Based on this analysis, a more effective global response to AMR requires strengthening the legal architecture at all levels.

### 7.1 International Level

Explore a Binding International Legal Framework: Begin diplomatic negotiations for a framework convention on AMR, similar to the Framework Convention on Tobacco Control. This could establish core obligations on surveillance, reporting, regulating antimicrobial use in humans and animals, and environmental management, while allowing flexibility for national circumstances (Hoffman *et al.*, 2015; Ugwu *et al.*, 2025b; Amadi *et al.*, 2017; Nwike *et al.*, 2017).

Strengthen the IHR: Amend the International Health Regulations to explicitly include AMR as a core capacity requirement, mandating countries to develop and fund surveillance and containment programs.

Create a Global Fund for AMR R&D: Establish an international pooled fund, financed by member states, to support push and pull incentives for the development of and equitable access to new antibiotics, diagnostics, and vaccines.

### 7.2 National Level

Enact Comprehensive Legislation: Countries should pass overarching "One Health" AMR laws that mandate coordination between human health, animal health, and environmental agencies. This legislation should:

Formally adopt National Action Plans and provide dedicated funding.

Mandate integrated surveillance systems.

Legislate strict prescription-only requirements for human and veterinary antimicrobials, backed by strong enforcement.

Ban the use of medically important antibiotics for growth promotion and strictly regulate their prophylactic use.

Implement mandatory antimicrobial stewardship programs in all hospitals and long-term care facilities.

Invest in Regulatory Capacity: Allocate resources to build the capacity of drug regulatory authorities, veterinary services, and environmental protection agencies to monitor compliance and enforce laws.

Implement National Pull Incentives Developed countries should pioneer new models for funding antibiotic innovation, such as market entry rewards or subscription models, to demonstrate feasibility and create a pipeline of new drugs.

### 7.3 Cross-Cutting Measures

Public Engagement: Laws should be complemented by sustained public awareness campaigns to change behaviors and build support for regulatory measures.

Global Equity: Any international financing mechanism for R&D must include strong provisions for ensuring affordability and access for LMICs, perhaps through tiered pricing or voluntary licensing agreements.

## 8.0 CONCLUSION

Antimicrobial resistance is a quintessential global public health crisis that exposes the limitations of our current governance systems. The public health community has clearly outlined the necessary technical steps to mitigate AMR: surveillance, stewardship, infection prevention, and innovation. However, the widespread and inconsistent implementation of these measures reveals a critical failure of law and policy. The existing legal landscape is a patchwork of non-binding international plans, uneven regional regulations, and divergent national laws, often crippled by inadequate enforcement and a lack of cross-sectoral integration. The "One Health" approach remains more of an aspirational concept than a legal reality in most jurisdictions.

To avert the looming AMR crisis, the world must transition from soft law recommendations to hard law obligations. This requires political courage to enact and enforce stringent regulations on antimicrobial use in human and animal sectors, to invest in environmental protection, and to create new economic models for antibiotic innovation that prioritize public health over market returns. The European Union's regulatory success offers a proven model, while experiments like the UK's subscription model provide a path forward on innovation.

Ultimately, defeating AMR is not just a scientific or medical challenge; it is a test of global governance, political will, and our ability to use the force of law to protect a common good—the enduring efficacy of antimicrobials for future generations. The time for incremental action has passed. A comprehensive, legally fortified, and equitably financed "One Health" response is not an option but an urgent necessity.

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