

Regulation of Antibiotics and Antimicrobial Resistance Laws: A Comparative Legal and Public Health Analysis

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ABSTRACT

Antimicrobial resistance (AMR) is one of the greatest public health and legal crises of the twenty first century and threatens the efficacy of medicines that have revolutionised twenty first century medicine, namely antibiotics. Its indiscriminate prescription, easy availability without prescription, unjustified use in medicine, its overuse in veterinary medicine and in agriculture has led to the emergence of resistant microorganisms that have caused high morbidity, mortality, longer hospitalizations and significant economic losses. AMR is recognized as a transboundary risk (TBR) and is the subject of coordinated legal and policy action based on a One Health approach under the leadership of international organizations, including the World Health Organization (WHO), Food and Agriculture Organization (FAO), the World Organisation for Animal Health (WOAH) and the United Nations (UN). This paper will critically look at the international and national legal and regulatory landscape for antibiotics and antimicrobial resistance, especially in India's developing legislation and policy space. It reflects regulatory aspects of antibiotic production, use, distribution, surveillance, antimicrobial use management and regulatory difficulties. The study carries out a comparative analysis of the doctrine and policy, highlighting the gaps for effective implementation, co-ordinated institutional approach and monitoring systems, and weak compliance mechanisms still affecting AMR control. Finally, the paper calls for more robust laws and inter-

country collaboration, unified surveillance programmes, good antibiotic governance, increased awareness of the public and a sustainable antimicrobial effectiveness for future generations.¹

Keywords: Antimicrobial Resistance (AMR), Antibiotic Regulation, Antimicrobial Stewardship, One Health Approach, Public Health Law

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1. INTRODUCTION

Antibiotics have transformed the way bacterial infections are treated and controlled in medicine, allowing for the treatment of complicated medical procedures like surgery, organ transplants, chemotherapy and even intensive care, resulting in lower mortality rates and a greater life expectancy. Their extensive use and overuse have, however, led to the quick development of antimicrobial resistance (AMR), where microorganisms develop resistance to the effects of antimicrobial agents. AMR is now a key public health problem as it compromises the availability and successful use of current drugs, contributes to higher healthcare expenses, longer hospitalizations, and higher morbidity and mortality death rates. AMR is officially recognized as one of the largest threats to global health, necessitating a multi-sectoral approach to tackle the issue among human health, animal health, agriculture and environmental practices.²

Regulations against the use of antibiotics cover aspects of more than just pharmaceutical control, including legal measures against prescription practice, manufacturing standards, distribution, surveillance, the prevention of infection and antimicrobial stewardship. In India the legal provisions cover the Drugs and Cosmetics Act 1940, Drugs Rules 1945, Schedule H and Schedule H1 provisions, National Action Plan on Antimicrobial Resistance and various public health policies related to rational antibiotic use. However, sales through OTC outlets, self-medication, weak regulation, counterfeit medicines and overuse of antibiotics in animal husbandry still hinder the effectiveness of regulation. It presents an overview of the legal and policy landscape related to antibiotic drugs management and AMR, and highlights current implementation weaknesses and recommendations for improvements and strengthening of the legal framework to promote AMR sustainable stewardship, in alignment with international best practices.³

2. CONCEPTUAL FRAMEWORK OF ANTIBIOTICS AND ANTIMICROBIAL

Table 2.1: Conceptual Framework of Antibiotics and Antimicrobial Resistance

RESISTANCE (AMR)

Antibiotics are medicines which specifically kill or slow the growth of bacteria (bacteriostatic medicine) and help prevent or cure bacterial infections. Antibiotics, synthesized since the discovery of penicillin in 1928, have been vital to medicine and are used today to treat many infectious diseases and allow for such complex treatments as organ transplants, chemotherapy, and some types of surgery. However, the inappropriate use of these products, such as over-prescription, self-medication, incomplete treatments, inappropriate use in livestock and agriculture, etc., has helped to drive the rise of antimicrobial resistance (AMR). AMR refers to exposure of bacteria, viruses, fungi or parasites to antimicrobial medicines, which make them resilient to the medicines, thus making it more likely that the disease will be spread, serious and harmful, and may result in the death of the treated person.⁴

AMR only conforms with a conceptual framework that takes into account that resistance is not only a medical and health problem but also a legal, regulatory, environmental and socio-economic problem. The One Health approach focuses on the interdependence and interconnectedness of human, animal and environmental health in tackling AMR. Comprehensive laws that cover the production, prescription, distribution, surveillance, prevention of infection and management of waste from antibiotics, along with governance to ensure proper surveillance or stewardship, are therefore essential for effective governance. Globally, practice and promotion of responsible antibiotic use is supported by coordinated legal frameworks were been advocated by international organisations including the World Health Organisation (WHO), Food and Agriculture Organisation (FAO), World Organisation for Animal Health (WOAH), and the United Nations. A strong regulatory system is essential to safeguarding future generations' access to effective antibiotics, while keeping medicines affordable and accessible to all.⁵

Component	Description	Legal/Policy Significance
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¹World Health Organization (WHO), *Global Action Plan on Antimicrobial Resistance* (WHO, Geneva, 2015)

² Government of India, *The Drugs and Cosmetics Act, 1940* (Act No. 23 of 1940).

³ Government of India, *The Drugs and Cosmetics Rules, 1945*.

⁴ Ministry of Health and Family Welfare, Government of India, *National Action Plan on Antimicrobial Resistance (2017–2021)*.

⁵ World Health Organization, “Antimicrobial Resistance,” WHO Factsheet (2023).

Antibiotics	Medicines used to treat bacterial infections	Regulated through pharmaceutical and drug control laws
Antimicrobial Resistance (AMR)	Ability of microorganisms to resist antimicrobial drugs	Requires national and international legal intervention
Causes of AMR	Overuse, misuse, self-medication, agricultural use, poor infection control	Necessitates stricter regulatory oversight
One Health Approach	Integrates human, animal, and environmental health	Forms the basis of global AMR governance

Antimicrobial Stewardship	Rational use of antibiotics in healthcare settings	Supported through hospital policies and legal standards
Surveillance Systems	Monitoring antibiotic use and resistance patterns	Essential for evidence-based policymaking
Regulatory Authorities	Drug regulators, public health agencies, veterinary authorities	Responsible for licensing, monitoring, and enforcement
Public Health Objective	Preserve antibiotic effectiveness and protect population health	Achieved through comprehensive legal and policy frameworks

3. EVOLUTION OF ANTIBIOTIC REGULATION AND ANTIMICROBIAL RESISTANCE (AMR) GOVERNANCE

The regulation of antibiotics has changed considerably since they were first discovered by Alexander Fleming in 1928 and started being used in clinic during the 1940s. Early focus of regulation concentrated on ensuring the quality, safety and efficacy of antibiotics on a pharmaceutical level and the standards of production. This excessive and irrational use of antibiotics in human medicine, veterinary and agriculture practice has hastened the development of antimicrobial resistance (AMR). In the late 20th century, government and nongovernment agencies and organizations began seeing AMR as not simply a health issue, but a global public health (and governance) problem, necessitating coordinated legal responses. However, countries reinforced the regulation of prescription, surveillance, pharmacovigilance and

Figure 3.1: Evolution of Antibiotic Regulation and AMR Governance

Period /Year	Major Development	Key Regulatory/Governance Change	Significance for AMR
Pre-1940s	Discovery and early use of antimicrobial agents	Limited regulation; antibiotics were not yet widely available	Established the foundation for modern antimicrobial therapy

limitations on OTC antibiotic use.⁶

AMR governance has evolved in the twenty-first century to become an integrated, trans-disciplinary approach. In the past, the One Health approach has been championed by the World Health Organization (WHO), Food and Agriculture Organization (FAO), World Organisation for Animal Health (WOAH) and the United Nations, acknowledging that human, animal, and environmental health are all interrelated. AMR has led many countries, such as India, to create National Action Plan on AMR, antimicrobial stewardship programmes, and enhanced pharmaceutical regulations that promote responsible antibiotic use. Modern governance of AMR prioritizes inter-agency coordination, surveillance, law enforcement, public education on AMR, and sustainable health policies that ensure the continued efficacy of antibiotics and reduce the risk of AMR spreading.⁷

1940s–1950s	Beginning of the antibiotic era and mass production	Governments began regulating drug safety, quality, and manufacturing	Widespread antibiotic use created the conditions for selection of resistant organisms
1960s–	Recognition	Stronger	Shift

⁶ Food and Agriculture Organization (FAO), *The FAO Action Plan on Antimicrobial Resistance 2016–2020* (Rome, 2016).

⁷ World Organisation for Animal Health (WOAH), *The WOAH Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials* (Paris, 2023).

1970s	ion of antibiotic resistance as a growing problem	national drug-control systems and prescription requirements developed	from viewing antibiotics only as medicines to recognizing risks of misuse
1980s–1990s	Expansion of antimicrobial use in humans, livestock, and agriculture	Increased attention to veterinary drug regulation and antimicrobial residues	AMR increasingly recognized as a cross-sectoral problem
1998	WHO established a global strategy for containment of AMR	International surveillance and rational antimicrobial-use policies promoted	Strengthened global coordination against AMR
2000s	Growth of AMR surveillance and antimicrobial stewardship	Countries developed national AMR action plans, prescribing guidelines, and surveillance systems	Focus expanded toward prevention, monitoring, and responsible antibiotic use
2011	WHO World Health Day focused on antimicrobial resistance	Global political and public awareness increased	AMR became a major international health-policy priority
2014	WHO published the first major Global Report on AMR	Global surveillance of resistance and antimicrobial consumption was emphasized	Demonstrated the scale and worldwide distribution of AMR

2015	WHO adopted the Global Action Plan on AMR	Five objectives introduced, including surveillance, stewardship, infection prevention, and research	Established a comprehensive global framework for AMR governance
2016	UN General Assembly High-Level Meeting on AMR	AMR was elevated to the international political agenda	Strengthened multisectoral and global commitment
2017	WHO launched GLASS (Global Antimicrobial Resistance and Use Surveillance System)	Countries encouraged to systematically collect and share AMR and antimicrobial-use data	Improved international surveillance and evidence-based policy
2019	Codex Alimentarius adopted guidance on AMR	Food and agricultural sectors incorporated AMR risk management	Reinforced the One Health approach
2020s	Increasing emphasis on One Health governance	Human health, animal health, food systems, agriculture, and environmental sectors increasingly coordinated	AMR governance became broader than healthcare alone
2022	Quadripartite collaboration strengthened	WHO, FAO, WOA, and UNEP worked jointly on AMR under a One Health framework	Integrated human, animal, food, and environmental dimensions
2024	UN High-Level Meeting on AMR	Global leaders renewed commitments to reduce AMR and improve	AMR governance moved toward measurable

		surveillance, prevention, and access to antimicrobials	ble global targets
2025– 2026	Impleme ntation and monitori ng of global	Greater emphasis on national action plans, antimicrobial stewardship,	Current governance focuses on translati

	AMR commit ments	surveillance, innovation, and accountability	ng global commit ments into national and sector- specific action

4. INTERNATIONAL LEGAL FRAMEWORK ON ANTIMICROBIAL RESISTANCE (AMR)

Transboundary public health issue cannot be addressed by single countries, antimicrobial resistance (AMR) is it. To encourage coordinated action on coordinated use of antibiotics and the dissemination of resistant micro-organisms, therefore, some international organisations have established legislation and policy. The World Health Organization (WHO) has taken the lead with the Global Action Plan on Antimicrobial Resistance (2015) which urges WHO member states to implement: enhanced monitoring; optimal antimicrobial use; infection prevention; and investments in research and innovation. This is complemented by the Food and Agriculture Organization (FAO) and the World Organisation for Animal Health (WOAH) working on One Health, with a recognition that human, animal and environmental health are interlinked. AMR has also been highlighted by the United Nations General Assembly as a global problem that calls for cooperation and aggression to create sustainable antimicrobial governance. Furthermore, the Codex Alimentarius Commission has adopted guidelines to control the use of antimicrobials in food-producing animals and the presence of antimicrobial residues in the food chain.⁸

Most international instruments on AMR are not legally-binding treaties but soft law documents which nonetheless have a strong impact on the laws, policies and approaches of national governments and public health strategies. Countries are advised to work on the following areas to build their National Action Plans, strengthen AMR programmes, enhance laboratory monitoring, control the sale of antibiotics and encourage responsible practices of pharmaceuticals. Cooperation on research, data exchange, capacity development and standardized regulations in the use of antibiotics is still vital to maintaining efficacy and global health security.⁹

5. NATIONAL LEGAL FRAMEWORK GOVERNING ANTIBIOTICS AND ANTIMICROBIAL RESISTANCE (AMR)

In order to manage antimicrobial resistance (AMR) and

ensure public health protection, India has laid down a robust legal and regulatory framework covering antibiotic manufacture, distribution, prescription and use. The main Act of Parliament relevant to the pharmaceuticals is the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 related to the approval, licensing, quality control, manufacture, sale and distribution of pharmaceuticals. To limit the indiscriminate use of antibiotics, licence categories H, H1 and X have been created and mandated restricting the dispensing of certain antibiotics without a valid prescription, and stipulate that pharmacists keep records of targeted antibiotics exposed. The One Health approach was incorporated in the National Action Plan on Antimicrobial Resistance (2017-2021) and additional national Action Plans have been developed that focus on improving surveillance, antimicrobial stewardship, infection prevention, raising public awareness, and promoting intersectoral coordination.¹⁰ Central approved regulatory bodies such as the Central Drugs Standard Control Organisation (CDSCO), the National Centre for Disease Control (NCDC), the Indian Council of Medical Research (ICMR) and the Food Safety and Standards Authority of India (FSSAI) are crucial in implementing these measures. Though these laws exist, a great deal of enforcement issues still exist. Antibiotics are still being sold over the counter, people are self-medicated, irrational use of antibiotics, counterfeit antibiotics, poor monitoring and over-use of antibiotics in animal food production are all ongoing drivers of AMR. Improved regulatory enforcement, but not quite everywhere, and reduced inspection capacity also limits the effectiveness of current regulations. To keep antibiotics effective in India, it is vital to: strengthen enforcement, digital prescribing, enhance lab surveillance, increase antimicrobial stewardship programmes, and raise awareness of prescribing and antibiotic use among the public.¹¹

6. REGULATORY MECHANISMS FOR ANTIBIOTIC PRESCRIPTION, DISTRIBUTION, AND USE

The proper control of antibiotic prescription,

⁸ United Nations General Assembly, *Political Declaration of the High-Level Meeting on Antimicrobial Resistance*, A/RES/71/3 (2016).

⁹ United Nations Environment Programme (UNEP), *Bracing for Superbugs* (Nairobi, 2023).

¹⁰ Indian Council of Medical Research (ICMR), *AMR Surveillance and Research Network Annual Report* (2023).

¹¹ Antimicrobial Resistance Collaborators, “Global Burden of Bacterial Antimicrobial Resistance in 2019,” (2022) 399 *The Lancet* 629.

distribution and use is essential to successful antimicrobial resistance (AMR) control and patient safety. Antibiotics in India are controlled by a combination of Statutory Control, Professional Standards and Public Health Policies. Pharmacists are expected to keep records of the dispensing of drugs under the specific schedules and books of prescription only; and prescription only drugs listed under Schedule H and Schedule H1 of Drugs and Cosmetics Rules, 1945 can be dispensed only by the prescription of a registered medical practitioner. Manufacturers, wholesalers and retailers must be licensed and all antibiotics manufactured are required to meet the Standards for Quality, Safety and efficacy. There are regulatory bodies such as the Central Drugs Standard Control Organization (CDSCO), and State Drug Control Departments to monitor the production and distribution of pharmaceuticals, as well as to take action in the case of counterfeit or substandard medicines.

Table 6.1: Regulatory Mechanisms for Antibiotic Control

Regulatory Mechanism	Purpose	Expected Outcome
Prescription-only regulation (Schedule H/H1)	Restrict unauthorized access to antibiotics	Reduce self-medication and misuse
Drug manufacturing licensing	Ensure quality, safety, and efficacy	Prevent circulation of substandard medicines
Pharmacy record maintenance	Monitor dispensing of critical antibiotics	Improve regulatory oversight and traceability
Antimicrobial Stewardship Programmes (ASP)	Promote rational prescribing in healthcare	Reduce inappropriate antibiotic use

7. ANTIMICROBIAL STEWARDSHIP, SURVEILLANCE, AND ONE HEALTH APPROACH

Today, the 3 key pillars in the governance of antimicrobial resistance (AMR) are antimicrobial stewardship, surveillance and the One Health approach. Antimicrobial stewardship (AMS) is a coordinated suite of interventions aimed at ensuring effective choice, doses, durations and treatment of antibiotics toward their most effective use while reducing the risk of development of resistant microorganisms. Hospitals and healthcare institutions use evidence-based treatment guidelines, audit prescription patterns, implement infection prevention strategies and provide ongoing education to healthcare professionals to

Hospitals adopt antimicrobial stewardship programmes with a focus on evidence-based prescribing, preventing infection and reviewing the use of antibiotics periodically. Patients are also reminded to avoid self-medication and to adhere to the course of treatment by public health campaigns to limit the development of resistant microorganisms.¹²

Although these regulations have been put in place, a number of problems remain in implementation. Irrational prescribing, medication access over the counter, and distribution of medicines online without proper verification process, and poor surveillance of antibiotic use in agriculture and veterinary medicine remain problematic threats to regulation. There is a need to strengthen digital prescription systems, hold pharmacists more accountable, increase surveillance and increase penalties for non-compliance with regulations to encourage responsible antibiotic use and limit the impact of antimicrobial resistance.¹³

	institutions	
Regulatory inspections	Ensure compliance by manufacturers and pharmacies	Strengthen enforcement of drug laws
Surveillance of antibiotic consumption	Track prescribing and resistance patterns	Support evidence-based policymaking
Public awareness campaigns	Educate citizens on responsible antibiotic use	Improve compliance and reduce misuse
Veterinary and agricultural regulation	Control antibiotic use in animals and food production	Minimize development of resistance across the One Health spectrum

implement stewardship programmes. AMR surveillance is also important, as it entails the coordinated and systematic gathering, analysis and sharing of data on antibiotic use and resistance. Good surveillance helps make decisions about emerging resistance to drugs and patterns, assess the effectiveness of regulatory measures, and develop public health policies and laws that are grounded in scientific evidence. Here, the Indian Council of Medical Research (ICMR) and the National Centre for Disease Control (NCDC) are pivotal organizations for

¹² Ramanan Laxminarayan et al., “Antibiotic Resistance—The Need for Global Solutions,” (2013)
¹³ *The Lancet Infectious Diseases* 1057.

¹³ A. H. Holmes et al., “Understanding the Mechanisms and Drivers of Antimicrobial Resistance,” (2016) 387 *The Lancet* 176.

bolstering AMR surveillance networks in India.¹⁴ The One Health approach takes an integrated approach to human and animal health, agriculture and environmental ecosystems. Thus, there is a need for countries to take coordinated measures against AMR to control its use in human medicine, in veterinary care, livestock production, aquaculture, and environmental waste management across these sectors. WHO, FAO, WOA and UNEP, among others, promote the concept of integrated governance for One Health. Support must be provided for adequate intersectoral coordination, strengthening laboratory capacity, improving surveillance systems, and complying with laws and regulations to ensure antibiotic efficacy and global public health security are achieved.

8. CHALLENGES, FINDINGS AND POLICY RECOMMENDATIONS

In spite of the important strides made in establishing legal and policy arenas for controlling antibiotics and tackling antimicrobial resistance (AMR), concerns remain about the progress and the obstacles that policy implementation must overcome. An irrational and excessive use of antibiotics in human medicine, veterinary and agricultural applications is one of the most persistent issues. The antibody resistance occurs because the antibiotic is accessible over the counter, they can self-medicate, unnecessary prescription and the demand by patients for the antibiotic contribute largely in achieving the resistant microorganisms.¹⁵

Weak regulation of pharmaceuticals, weak monitoring of e-sales of medicines, and the movement of counterfeit and substandard medicines further limits effectiveness of pharmaceutical regulation. In addition, there are differences in healthcare infrastructure, limited capacity in laboratories, inadequate surveillance systems and a lack of trained healthcare workers which hinder prompt detection and management of resistant infections. The study identifies three indicators that low and inconsistent implementation of international organisations' policy frameworks using the World Health Organisation (WHO), Food and Agriculture Organisation (FAO), World Organisation for Animal Health (WOAH) and the United Nations as examples is in place at the national level: while there are some excellent policy

frameworks in place, they show inconsistencies; the consistency of implementation is repeatedly compromised by lack of agreement within policy development processes; and there are gaps in the profiles of national animal health policies. India has extensive laws to the effect such as Drugs and Cosmetics Act, 1940, Drugs and Cosmetics Rules, 1945, and the National Action Plan on AMR to have a solid regulation system. But these measures have limited effectiveness due to state inconsistencies, inadequate inter-departmental coordination, lack of public awareness and lack of implementation of the One Health approach.¹⁶

Although the number of surveillance systems has grown significantly, there are limitations in data sharing, laboratory standardization, and the ability to monitor antimicrobial consumption in both human and animal health areas. Government should consider a more holistic and integrated approach to AMR governance, and include measures such as regulatory action with interventions in the public health domain. Striking enforcement of prescription only policies should be done by making good use of digital prescription systems and improving the accountability of pharmacists. Efforts to improve the capacity of national AMR surveillance networks by building on current infrastructure and installing real-time reporting mechanisms are needed to effectively monitor antimicrobial consumption and resistance trends.¹⁷

Hospitals need to incorporate antimicrobial stewardship programmes with regular audits of prescription, clinical antimicrobial guidelines and ongoing education of their staff. Addressing the issue of antibiotic use in livestock, aquaculture and agriculture through regulatory systems should be strengthened based on the One Health approach. There is also a need to invest more in research and development of new antimicrobial products, quick diagnostic methods, vaccines and the development of alternate antivirals. In conclusion, it is crucial to ensure that their effectiveness does not diminish, public health is safeguarded, and antimicrobial governance be sustained for future generations through ongoing public awareness and education initiatives, global collaboration, and aligned regulations.¹⁸

Table 8.1: Challenges, Findings, and Policy Recommendations for Antibiotic Regulation and Antimicrobial Resistance (AMR)

Challenges	Key Findings	Policy Recommendations
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		ons
Irrational and excessive antibiotic	Misuse in hospitals, community healthcare,	Enforce rational prescribing through antimicrobial

¹⁴ C. L. Ventola, "The Antibiotic Resistance Crisis: Causes and Threats," (2015) 40 *Pharmacy and Therapeutics* 277.
¹⁵ F. Presti Naci, P. Pezzotti & A. Pantoate, "Antimicrobial Resistance: A Global Multifaceted Phenomenon," (2015) 109 *Pathogens and Global Health* 309.

¹⁶ Centres for Disease Control and Prevention (CDC), *Antibiotic Resistance Threats in the United States* (2024).
¹⁷ European Centre for Disease Prevention and Control (ECDC), *Antimicrobial Resistance Surveillance in Europe* (2023).
¹⁸ World Health Organization, *Global Antimicrobial Resistance and Use Surveillance System (GLASS) Report* (2024).

use	and self-medication accelerates AMR	stewardship programmes and clinical guidelines
Over-the-counter sale of antibiotics	Inadequate compliance with prescription-only regulations leads to uncontrolled antibiotic access	Strengthen enforcement of Schedule H/H1 provisions and implement digital prescription verification
Weak regulatory enforcement	Existing drug laws are comprehensive but implementation remains inconsistent across states	Increase inspections, regulatory audits, and penalties for violations
Counterfeit and substandard medicines	Poor-quality antibiotics contribute to treatment failure and resistance	Strengthen pharmaceutical quality control and supply chain monitoring
Inadequate AMR surveillance	Limited laboratory capacity and fragmented reporting reduce early detection of resistance	Expand national surveillance networks with real-time digital reporting systems
Excessive antibiotic use in livestock and agriculture	Non-therapeutic use contributes to transmission of resistant microorganisms	Regulate veterinary antibiotic use under the One Health framework and prohibit indiscriminate use
Limited public awareness	Poor understanding of antibiotic misuse results in	Conduct nationwide public awareness and educational campaigns on

	self-medication and incomplete treatment	responsible antibiotic use
Inadequate hospital antimicrobial stewardship	Many healthcare institutions lack standardized stewardship programmes	Make antimicrobial stewardship programmes mandatory in all healthcare facilities
Weak intersectoral coordination	Fragmented governance among health, veterinary, agricultural, and environmental agencies limit effective implementation	Strengthen coordination through integrated One Health governance mechanisms
Insufficient research and innovation	Slow development of new antibiotics and diagnostic technologies weakens long-term preparedness	Increase investment in antimicrobial research, rapid diagnostics, vaccines, and alternative therapies
Inconsistent international cooperation	Variations in national policies hinder effective global AMR control	Promote harmonized international legal standards, data sharing, and collaborative research
Environmental contamination with antibiotics	Pharmaceutical waste and hospital effluents contribute to environmental reservoirs of resistance	Enforce environmental regulations for safe disposal of pharmaceutical and biomedical waste

9. CONCLUSION

Antimicrobial resistance (AMR) is one of the biggest public health and regulatory problems that are facing the global community. To face the threat of decades of medical progress, the widespread use and misuse of anti-biotics in healthcare, veterinary and agricultural medicine, as well as in the environments in which plants and animals live, has facilitated the emergence

of resistant microorganisms. Regulating antibiotics is certainly not just about regulating pharmaceuticals but an integrated approach involving prescription regulation, manufacturing standards, surveillance systems, antimicrobial stewardship, infection prevention and control and environmental management are required. WHO, FAO, WOA, UNEP and the United Nations have chaired several international

initiatives that have developed a rich policy background in adopting a One Health approach to the governance of antimicrobial use, motivating Member States and countries of origin to enhance regulation of antimicrobial use and the responsible use of AMR at a national level.

India has established a broad-based legal and institutional framework comprising two Acts: Drugs and Cosmetics Act, 1940 and Pharmacovigilance Guidelines, 2022 along with two Rules: Drugs and Cosmetics Rules, 1945 and Schedule H and H1 regulations, and the National Action Plan on Antimicrobial Resistance. More than that, however, there are endemic issues of irrational prescribing, self-medication, OTC sales of antibiotics, counterfeit drugs, and high livestock use of antibiotics which are reducing the effectiveness of regulation. This will depend on increased legal compliance, better surveillance systems, the digitisation of prescriptions, strengthening of laboratory infrastructure, effective antimicrobial stewardship programmes, and better coordination of and communication between health, veterinary, agricultural and environmental authorities.

For future research and development, legal oversight, scientific progress and cooperation among nations all play a critical role in the sustainable control of AMR. Policies need to focus on funding for research, public awareness, and regulation, to help promote access to effective antibiotics while protecting public health and supporting regulatory capacity. The adoption and implementation of the One Health approach with a full harmonisation of the national laws with the international standards will promote global preparedness for-resistant pathogens. The ability to maintain the effectiveness of antibiotics, resist the threat of untreatable infection in future generations and safeguard the health sector's resilience to meet the challenge of antimicrobial resistance is essential and can only be provided by a multidisciplinary and legally responsible response.

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