REVIEW ARTICLE

Optimized Regulatory and Industry Strategies for Combating Antimicrobial Resistance: A Harmonized Approach

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Abstract

Antimicrobial resistance (AMR) represents a critical global health challenge threatening the effectiveness of modern medicine. The rapid rise of resistant pathogens, coupled with a slow pipeline of new antimicrobials, necessitates coordinated regulatory and industrial responses. This review critically evaluates regulatory frameworks, pharmaceutical industry responsibilities, antimicrobial stewardship programs, and surveillance systems as integrated strategies for AMR mitigation. Special emphasis is placed on good manufacturing practices, environmental risk control, and responsible antibiotic distribution to minimize subtherapeutic exposure and contamination. Global initiatives and One Health interventions are discussed. This review uniquely integrates regulatory science, industrial compliance, and One Health strategies into a harmonized AMR governance model. A coordinated framework integrating regulatory enforcement, industry accountability, and cross-sector collaboration is proposed as a sustainable pathway for AMR containment.

Key words: Antibiotic stewardship, antimicrobial resistance, novel antimicrobials, pharmaceutical industry, public–private partnerships, regulatory framework

INTRODUCTION

The issue of antimicrobial resistance (AMR) has gained international attention. In both human and veterinary medicine, it threatens the application of antibiotics along with additional antimicrobial medicines.[1] With rising rates of morbidity and death, as well as a global financial burden, the rise of these therapy-resistant pathogenic microbes poses a major threat to the healthcare system. AMR has the potential to destroy decades of advancements in medicine and transform once-treatable illnesses into potentially fatal conditions if appropriate action is not taken. Lack of research into novel antimicrobial agents, inadequate surveillance, improper use and overuse of antibiotics in treatment, and lax enforcement of antimicrobial agent regulations all contribute to the rising issue of resistance.[2] To effectively combat AMR, regulatory agencies, pharmaceutical companies, healthcare professionals, and policymakers should work together to achieve the same goal. AMR is the ability of bacteria, viruses, fungi, and parasites to adapt to the effects of antimicrobial agents that typically cure infections and other diseases. Resistance typically results from genetic changes in the living thing or the incorporation and development of resistance genes from other microbes.[3] The development of drug resistance is stimulated by an increase in the length of illness, hospitalization rate, treatment costs, and the risk of death.

The World Health Organization (WHO) has listed 11 dangers to global health, including AMR, underscoring the urgent need for coordinated measures to limit its consequences. AMR would result in a post-antibiotic future where ordinary illnesses cannot be cured, surgery is exceedingly dangerous, and advancements in critical care, cancer therapy, and organ transplantation are seriously jeopardized.[4] Therefore, in order to prevent AMR and protect public health, regulatory bodies and the pharmaceutical business must take the

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initiative. The European Medicines Agency (EMA), the U.S. Food and Drug Administration (FDA), the WHO, and other national health authorities are among the most significant organizations that deal with the policy-making process for antimicrobials in usage and manufacturing. The organizations provide guidelines to ensure that antibiotics are used appropriately, track patterns of resistance, and promote the development of novel treatment concepts.[5] The efficacy as well as safety of newer antibiotics is guaranteed before market introduction by a proper regulatory framework for antibiotic approval and market monitoring, which includes ongoing post-market surveillance to monitor new resistance trends. Since low-quality antibiotics lead to resistance by exposing pathogens to subtherapeutic concentrations of the drug, regulatory agencies also enforce strict quality control and good manufacturing practices (GMP) to prevent the entry of substandard or counterfeit drugs.

The implementation of antimicrobial stewardship programs (ASPs) in healthcare institutions is another important strategy for controlling AMR. To reduce antibiotic contamination, regulatory bodies must firmly enforce wastewater treatment regulations and promote the use of environmentally friendly disposal techniques.[6] Furthermore, it is crucial to set up an efficient monitoring system to keep an eye on antibiotic usage rates, resistance trends, and the appearance of risks. Efforts that enable data to be collected and shared around the world, including the Global Antimicrobial Drug Resistance and Use Monitoring System, are important parts of the early detection and intervention system. Since antibiotic metabolites in wastewater from pharmaceutical manufacturing plants and healthcare facilities contribute to AMR in the environment, environmental risk monitoring has also grown in importance. Artificial intelligence (AI)-driven models for prediction and genomic surveillance are examples of new monitoring and surveillance techniques that will improve AMR detection and response strategies. To maximize the use of antibiotics, the veterinary and health sectors should encourage sustainable antimicrobial stewardship.[7] Funds for AMR study and educational programs should be given top priority by policymakers to persuade the general public and healthcare providers to use antibiotics responsibly. In the end, such tactics would necessitate cooperation from all of the major AMR stakeholders, adherence to government regulations, and industry best practices. The long-term viability of AMR mitigation efforts will be made possible by making investments in cutting-edge technology, improving compliance procedures, and fortifying global governance.[8] Financial assistance, expedited approvals, and even longer patent protection will encourage pharmaceutical companies to devote their time and energy to developing novel antimicrobial remedies.

A comprehensive approach to addressing AMR requires collaboration between regulatory bodies, the pharmaceutical sector, healthcare providers, and legislators. Partnerships between the public and private sectors make it easier to share expertise, increase capacity, and fund AMR research. To guarantee that implementation is uniformly enforced across regions, international collaboration is also required to unify AMR rules.[9] Since antibiotics are typically used to stimulate growth and prevent disease in animals, they should also support policies that encourage the safe use of antibiotics in the veterinary and agricultural industries, in addition to in humans. The spread of resistance will be significantly reduced if the non-therapeutic use of antibiotics in animal husbandry is restricted and their substitutes are improved for infection control. To sum up, AMR is a complicated issue with many facets that can only be resolved by concerted efforts involving regulatory bodies, the pharmaceutical sector, medical professionals, and legislators. To reduce the hazards of AMR, it is essential to change regulatory frameworks, implement compliance procedures, and fund creative antimicrobial research.[10] By enforcing stringent antibiotic stewardship, enhancing surveillance systems, and encouraging responsible antibiotic use across all sectors, we can delay the emergence of resistance and maintain the effectiveness of currently available antimicrobials. Only a unified worldwide strategy that establishes the groundwork for sustained success against AMR and protection will make all of this feasible.

THE NECESSITY OF A COHESIVE REGULATORY AND INDUSTRIAL FRAMEWORK TO COMBAT AMR

AMR threatens the treatment effectiveness of antibiotics and other antimicrobials as they relate to diseases caused by bacteria, viruses, fungi, and parasites. AMR has rightly become one of the major global healthcare issues. Factors mainly responsible for an imminent widespread infection by resistant microorganisms are the rampant misuse of antibiotics in agriculture, human health, and veterinary treatment, alongside deficient regulation and lax adherence by the industry. The birth of an international body to harmonize all regulatory bodies and pharmaceutical organizations in matters concerning fighting AMR is very important, with the daily increase of AMR. Such partnerships, in essence, will manifest in a comprehensive framework of sensible regulations on antimicrobials covering effective antibiotic usage, manufacture, and surveillance. AMR can create untreatable illnesses, increase health expenditures, and also lead to greater morbidity and mortality without a clearly defined and coordinated strategy.[11] Developing and enforcing strict regulations governing the production, use, and distribution of antibiotics is the essential pillar of the AMR control strategy. WHO, FDA, and EMA set regulatory standards for monitoring antibiotic consumption, prevention of resistance, and many other issues. However, the main disadvantage is that different countries' laws and how these laws are enforced leave many gaps, allowing illegal importation of antibiotics worldwide. Regarding the above,

it is necessary to have a unified and hence global regulatory framework, that is, AMR regulations are uniform across all locations.

Moreover, they need to implement and develop sound mechanisms for continuous post-marketing surveillance so as to study in real time the use of antibiotics and trends for novel resistance emerging.[12] With its insistence on responsible manufacture and investment in research and development (R&D) for new antimicrobials, the pharmaceutical industry is a leading force for AMR remediation. The development of new antibiotics is challenged by high R&D costs, scant revenue from antibiotic sales, and complex regulations, prompting the delay of medicines from the market. These pharmaceutical companies must be encouraged to develop new antibiotics and other therapeutic systems through an amalgamation of incentives under a single program framework, which could include direct cash support, longer patent life, and expedited approval from regulatory authorities.[13,14] Further, environmental regulations aimed at controlling the release of certain antibiotics into the environment (into wastewater), thereby propagating resistance, also apply to pharmaceutical companies. Green industrial practices and novel wastewater treatment methods will help reduce some of the environmental-related AMR risk. One more linking element relates to the use of ASPs in the healthcare context.[15] These ASPs aim to prevent the overprescription of antibiotics and to educate healthcare professionals on the potential ramifications of antibiotic resistance. Meanwhile, the collaboration of regulatory agencies with hospitals, clinics, and pharmacists on the implementation of ASP guidelines and monitoring the relevant changes in the use of antibiotics is also crucial.[16] The responsible prescribing of antibiotics by healthcare professionals when indicated and the adherence to accurate dosage recommendations are also important to minimize resistance development in these pathogens. Public education campaigns should therefore be initiated regarding the hazards of self-medication with antibiotics and the importance of adherence to the prescribed treatment regimens. To provide a coherent response against the AMR, it can rely on surveillance systems and scientific data exchange.

The platform should enable the development of international databases gathering and analyzing trend data regarding antibiotic use, resistance, and emerging threats. Therefore, a consistent and worldwide framework should be put in place to build global databases for the study of antibiotic use, resistance trends, and new threats.[17] More initiatives in these areas are underway through organizations such as the WHO's Global AMR and Use Surveillance System (GLASS); however, there may be a need for collective international commitment to strengthen these initiatives. Real-time AMR data would enable countries to strategize interventions, understand resistance patterns, and provide solutions on time. These involve big data analytics and AI, which can also help in guaranteeing better accuracy for decision-making on AMR control and surveillance activities shown in Figure 1. Agriculture and veterinary uses of antibiotics contribute significantly to AMR-lending: Among the most common uses of antibiotics is the prevention of disease in animals. By exchanging real-time AMR data, countries are able to predict future trends of resistance, initiate early responses, and divert attention to other initiatives. Big data analytics and AI can also sharpen AMR containment surveillance in terms of accurate decision-making.[18] Because antibiotics are often used in animals for disease prevention and growth promotion, agricultural and veterinary uses are also significantly contributing to AMR. For the appropriate control of non-therapeutic application of antibiotics in animal farming and the promotion of alternative approaches to infection control, regimentation regarding the application of these interventions should really exist.[19]

These alternatives include farmers using probiotics, vaccines, and better general hygiene practices that reduce reliance on antibiotics while maintaining animal welfare and productivity. Non-therapeutic uses of antibiotics in animal husbandry should be relatively unrestricted in the single regulatory framework; yet, alternative strategies for preventing diseases should be encouraged so as to maintain animal health and productivity and to lessen reliance on antibiotics. Another key factor is the monitoring of residues in food commodities to prevent any antibiotic contamination of the food chain, thus exposing humans to resistant bacteria. The Joint Research and Funding for AMR Initiative would entail innovative partnerships between public and private organizations to produce new diagnostic tools for early identification of resistance. Such organisations with international credibility as WOAH, UN, and WHO must keep coordinating AMR strategies and provide technical assistance to developing countries shown in Table 1.[21] Lawmakers, veterinarians, and healthcare professionals must unite in initiatives to develop and implement antimicrobial stewardship and educate the public on appropriate antibiotic use. The existence of such a partnership and taking advantage of advances in technology will be critical to the success of creating a comprehensive framework to combat AMR and ensure the future of antimicrobial treatment.

STRICT ADHERENCE TO REGULATIONS AND GMP IN THE PRODUCTION OF PHARMACEUTICALS

Manufacturing of pharmaceuticals, distribution, and disposal of antibiotics are among the major contributors to AMR. AMR is turning out to be a global health problem, threatening the efficacy of antibiotics and other similar medications. This prompts inferior medicines being exposed to the community, pollution of the environment, and exposure to increased selection pressure for resistant microbes. Strict compliance with regulations, along with adherence to GMP in the manufacture and distribution of pharmaceuticals, renders these punishments minimal. Proper manufacture, controlled

storage, and dispensing under regulatory conditions lessen the chances of developing AMR. Regulatory bodies are vital in generating and implementing these guidelines, ensuring that manufacturers apply best practices to reduce the negative effects of pharmaceutical production on the general population.[31] Health care in the world, increasingly losing potency from antibiotics and other related medicines, is endangered by the burden of AMR. A major factor causing AMR is the manufacturing, distribution, and disposal of antibiotics in the wrong ways; this can lead to developing inferior medicines, contaminate the surroundings with such products, and even increase selection pressure in favor of resistant microbes. Compliance with these regulations alone and adherence to GMP are mandatory in pharmaceutical manufacturing to minimize the incidents mentioned above. AMR development would be reduced where antibiotics are manufactured, stored, and dispensed under regulated conditions that would maintain safety, efficacy, and quality. These regulatory bodies are crucial in the generation and enforcement of such guidelines, ensuring adherence on the part of the manufacturers toward the best practices to minimize the adverse impacts of pharmaceutical manufacture on the wider masses.[32]

Adherence to regulations in the production of pharmaceuticals

The pharmaceutical industry has to comply with laid-down regulations by national and international regulatory bodies. Agencies such as the World Health Organization, U.S. FDA, EMR, and International Council for Harmonization of Technical Requirements for Pharmaceuticals for Humans provide stringent guidelines that govern the manufacture and distribution of antibiotics. The regulations guarantee that pharmaceutical companies manufacture superior quality medicines concerning the safety and efficacy criteria. Further, preventing the circulation of counterfeit and substandard medicines, which subject microorganisms to inadequate drug concentrations and exacerbate AMR, is one of the other primary goals of regulators.[33] Regulatory bodies require the pharmaceutical companies to apply for licenses, be subjected to half-a-dozen inspections, and comply with an elaborate set of rules regarding documentation and reporting; only then can they undertake this role. Compliance with pharmacovigilance guidelines also implicatively calls for the monitoring of adverse reactions with drugs and the emergence of resistance. Technologies for post-marketing monitoring allow regulatory authorities to follow up on the efficacy of antibiotics and the emergence of newer trends of resistance to be appropriately notified. To harmonize across sites' compliance standards, a single global regulatory regime is required. The gaps in different countries' dissimilar regulations allow substandard antibiotics to seep into international markets. Worldwide collaboration among regulatory bodies would support the sharing of relevant knowledge for conducting joint inspections and standardizing approval processes, thus ensuring that antibiotics will meet strict quality criteria regardless of where they originate from.[34] Furthermore, regulatory bodies need to implement very serious sanctions in the case of non-compliance, including the revocation of licenses, the imposition of fines, and the blacklisting of manufacturers that contravene GMP.

GMPs in the production of antibiotics

In accordance with a set of principles, GMP serves to regularize the production and control of pharmaceuticals. GMP covers every area of manufacturing, including raw material procurement, equipment maintenance, employee training, quality assurance, and packaging. From the view of avoiding cross-contamination, ensuring product uniformity, and maintaining the therapeutic efficacy of drugs, GMP is essential for the manufacture of antibiotics. Keeping the manufacturing environment sterile is one of the basic principles of GMP. Antibiotic manufacturing contamination reckons some components through providing ineffectiveness of the drug-promoting cross-contamination with other pharmaceutical substances, or contamination to those that are useful for AMR-generating organisms.[35] Pharmaceutical facilities ought to observe strict hygienic practices, including aseptic processing, controlled air filtration systems, and routine sterilization of equipment. Employees involved in manufacturing should also receive comprehensive training on applying antimicrobial chemicals and preventing contamination. Quality control is another component of GMP. To reassure that antibiotics meet purposed requirements for potency, purity, and stability, manufacturers must establish validated in-process testing procedures. Advanced analytical methods for detecting contaminants and verifying the composition of final products must include mass spectrometry and high-performance liquid chromatography.[36]

Batch-to-batch consistency should be maintained to obviate differences in pharmacological effectiveness, so as not to cause resistance. Another important aspect of GMP is accurate record-keeping and documentation. These will help pharmaceutical firms trace back raw material sources, methods of production, quality control testing, and distribution. In the issue of product recalls, resistance epidemiological studies, and agency audits, these records ensure traceability. Digital record-keeping systems may further enhance transparency and reduce the risk of false documents. GMP Compliance with environmental risk management. This accounts for any environmental risks posed by antibiotic manufacture, as GMP should also cater to the manufacturer's environmental risk management. Public health faces serious threats when antibiotic residues are pointed toward effluent systems, breeding resistant bacteria.[37] Manufacturers have to comply with GMPs, which include waste management, control of effluent discharges, proper disposal of unwanted antibiotics, and compliance with the law in support of environmental protection.

GMP compliance with environmental risk management

Some materials and facilities manufacture antibiotics, but do not consider the environmental hazards caused by the manufacture of these products. Release of these residues into wastewater systems poses a serious public health risk because they become breeding grounds for resistant bacteria. Hence, the manufacturer must follow GMP parameters for waste management, which include effluent control, unwanted antibiotics disposal, and compliance with environmental protection legislation. Residues from antibiotics could be effectively removed before wastewater is discharged into the environment using advanced technologies for wastewater treatment, such as membrane bioreactors, activated carbon filtration, and advanced oxidation processes. Industries should just embrace the principles of green chemistry to reduce waste generation and lessen the environmental effect of antibiotic production. Regulatory agencies must, therefore, impose strict limits on antibiotic discharge levels to ensure compliance and conduct regular environmental monitoring.[38]

The role of technology in enhancing GMP compliance

The advancements in technology contribute to increasing adherence to GMP and maintaining the quality of antibiotic production. AI and automation improve quality control procedures, reduce human error, and enhance process efficiencies. Fulfilling these functions, real-time monitoring systems enable manufacturers to detect and act quickly on any deviations by monitoring critical parameters like temperature, humidity, and microbial contamination levels. Thus, blockchain can enhance pharmaceutical supply chain transparency by providing an immutable record for each antibiotic manufacturing step, from the sourcing of raw materials to final distribution. This way, it can ensure that all antibiotics comply with regulatory requirements, preventing counterfeit medicines from entering the market. AI-enabled predictive analytics can also help spot any issues with quality control before they snowball into something bad, thereby improving compliance with GMP overall.[39,40]

International cooperation and policy suggestions

International collaboration is essential for improving regulatory enforcement and compliance with GMP standards. The government, regulatory authorities, and pharmaceutical enterprises should partner in the establishment of standardized GMP rules within their countries, exchange of best practices, and provision of both financial and technical assistance to low-income countries in instituting a strict quality control system. All kinds would have much to gain from modern initiatives designed to improve capacity, financing of their companies in developing nations, and training opportunities for regulatory inspectors. Through public–private collaboration, innovative antibiotic formulations that have a lower likelihood of resistance development may be easily developed. Regulatory bodies should put in place for pharmaceutical companies that invest in green production technologies concessional loans, tax holidays, and fast-tracked approvals for grants in developed antibiotic production methods.[41]

REGULATORY POLICIES AND THEIR ROLE IN AMR MITIGATION

One of the best approaches to resistance to antibiotics is to establish stringent regulations that control the manufacture, usage, and distribution of antibiotics. Regulatory frameworks set up by national and international authorities are imperative to ensure the responsible use of antimicrobials while minimizing the risk of resistance development and maintaining therapeutically effective antimicrobials. Such policies cover a lot of topics, such as manufacturing standards, surveillance systems, antimicrobial stewardship initiatives, environmental restrictions, and medication licensing processes in their entirety.[42] Otherwise, AMR may develop into a public health emergency with dire consequences to the global healthcare system, food security, and economic stability. Regulating the distribution and licensing of antimicrobial medication is one of the major roles of regulatory policies in curbing AMR. Guidelines for the assessment and licensing of novel antimicrobials are established by agencies such as EMA, FDA, WHO, and national regulatory authorities. Before the commercialization of new antibiotics, these networks required evidentiary material demonstrating the effectiveness, safety, and need for such medicines in the market, as supplied by the pharmaceutical companies.[43] Furthermore, regulatory frameworks limit the use of important medicines to situations where no alternative therapies are available by classifying the value of antimicrobials to human health. This strategy lessens the possibility of resistance development by holding back last-resort medications for use in serious disease conditions. It is one of the best approaches to antibiotic resistance by introducing these stringent regulations that will monitor the production, application, and distribution of antibiotics.[44]

Regulatory frameworks equipped by national and international authorities are imperative to ensuring that antimicrobials are used very responsibly, but also importantly, to lowering the risk of their potential for developing resistance while conserving their therapeutic effectiveness. Policies cover such diverse areas as manufacturing standards, surveillance systems, antimicrobial stewardship initiatives, environmental restrictions, and drug licensing processes. Without clear binding regulatory regulations, AMR may evolve into a public health emergency with dire consequences for global healthcare, food security, and economic stability. Regulation concerning the distribution and licensing of antimicrobial drugs is one of the major contributions of regulatory policy to curtailing the incidence of AMR. Agencies such as EMA,

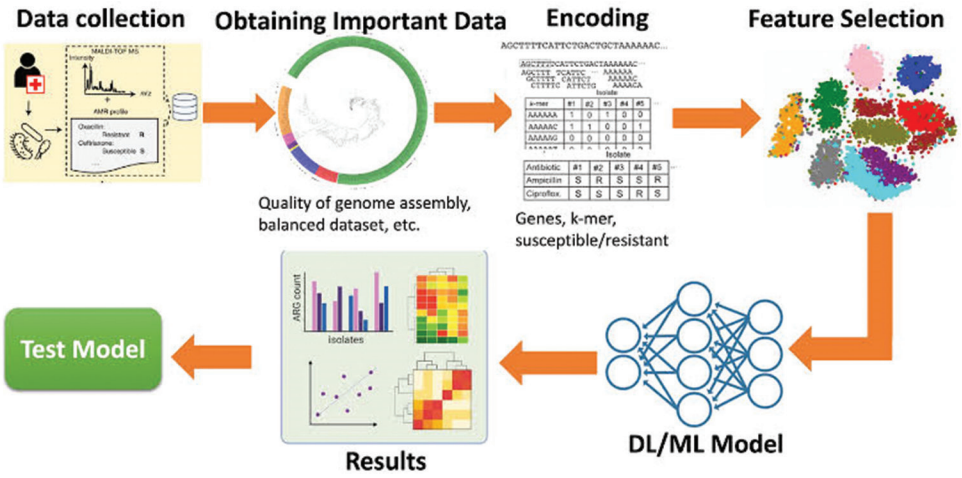


Figure 1: Artificial intelligence for antimicrobial resistance[20]

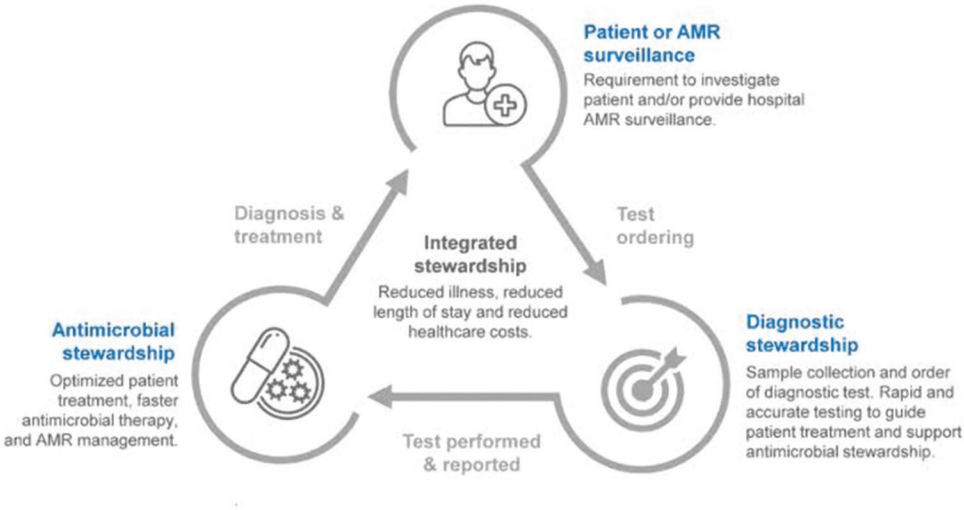
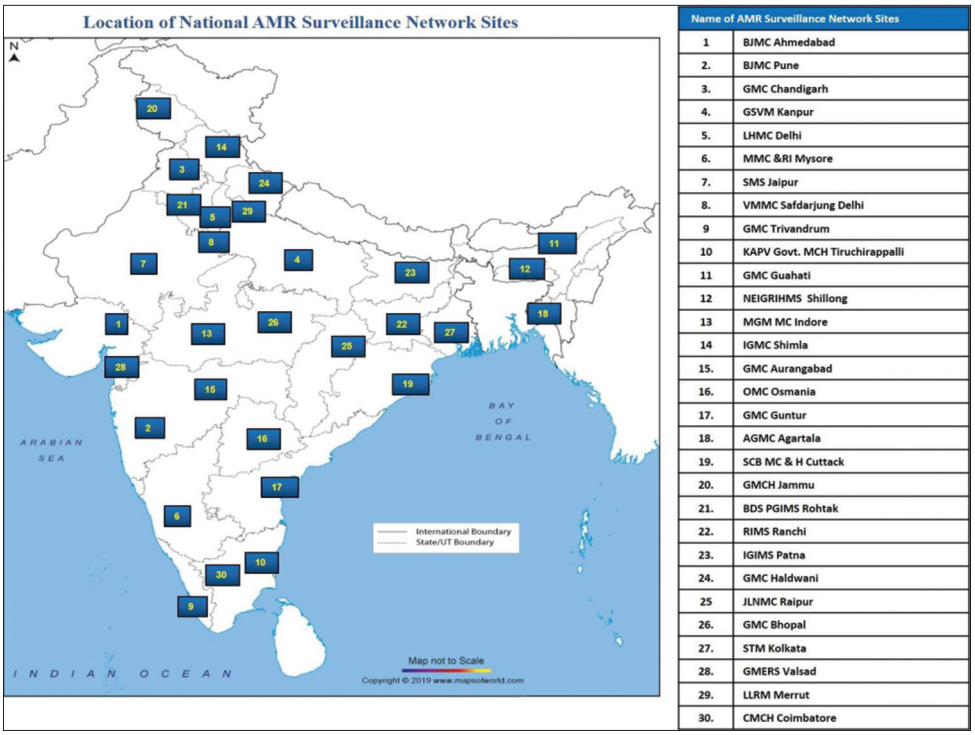


Figure 2: Prevention of antimicrobial resistance presented in World Antimicrobial Awareness Week 2022

Figure 3: Global antimicrobial resistance and use surveillance system

FDA, and WHO, among others, stipulate guidelines for the evaluation and licensing of new antimicrobials.[45] All these agencies require pharmaceutical companies to show efficacy, safety, and need before authorizing the marketing of new antibiotics. Besides, they further classify antimicrobials in line with their importance to human medicine to restrict their application to cases that do not have alternative therapeutic options. This approach will further minimize any chances for the development of resistance by reserving last resort medications for use in serious disease situations.

Controlling regulations in manufacturing and quality-related concerns are related to the most efficient possible prevention of AMR. Resistance may develop from subpar or counterfeit antimicrobials of questionable specification and may contain inaccurate examples, whereby the antifungal products are used for exercise. GMPs are regulatory-based principles that ensure these manufacturing standards are followed by pharmaceutical establishments.[46] Such regulations dictate methods of quality control, frequent inspection, and messy compliance with pharmacopoeial standards. With these regulations, the authentication of pharmaceutical products is highly assured. Regulatory authorities will guarantee antimicrobial medicines are



Name of AMR Surveillance Network Sites	
1	BJMC Ahmedabad
2.	BJMC Pune
3.	GMC Chandigarh
4.	GSVM Kanpur
5.	LHMC Delhi
6.	MMC &RI Mysore
7.	SMS Jaipur
8.	VMMC Safdarjung Delhi
9	GMC Trivandrum
10	KAPV Govt. MCH Tiruchirappalli
11	GMC Guahati
12	NEIGRIHMS Shillong
13	MGM MC Indore
14	IGMC Shimla
15.	GMC Aurangabad
16.	OMC Osmania
17.	GMC Guntur
18.	AGMC Agartala
19.	SCB MC & H Cuttack
20.	GMCH Jammu
21.	BDS PGIMS Rohtak
22.	RIMS Ranchi
23.	IGIMS Patna
24.	GMC Haldwani
25	JLNMC Raipur
26.	GMC Bhopal
27.	STM Kolkata
28.	GMERS Valsad
29.	LLRM Merrut
30.	CMCH Coimbatore

Figure 4: National antimicrobial resistance (AMR) surveillance network laboratories that have reported AMR surveillance data to the National Centre for Disease Control in the year 2020

labeled and packaged appropriately, providing consumers and healthcare professionals with appropriate information regarding dose, usage, and any resistance concerns. Another area that regulatory standards touch on is implementing ASPs in health care facilities. Regulation can be put in place by creating a main goal of safekeeping of antibiotics through appropriately recommending practices to physicians.[47] There, with hospitals, clinics, and pharmacies, one can enforce regulations preventing overprescribing, ensuring the right dosage, and encouraging narrow-spectrum antibiotics use when feasible. Policymakers can modify guidelines depending on real-time surveillance since regulations by regulatory authorities in many countries direct that healthcare facilities disclose statistics on antibiotic consumption, along with the trends of resistance. Continuing medical education programs on AMR are also necessary to enhance healthcare workers' understanding of resistance mechanisms and the importance of conserving antimicrobials. Antibiotics are used extensively to curtail disease and foster animal production; thus, the veterinary and agricultural use of antibiotics lies within the ambit of regulation.[48]

Since resistant microorganisms may traverse from animals to humans through direct contact, ingestion through food, and environmental contamination, antibiotic misuse in animal husbandry has recently received the spotlight as one of the major causes of AMR. Restrictions have been placed on the use of medically important antibiotics for animal production by various regulatory agencies in an attempt to ameliorate this problem. WHO and national governments have set forth guidelines that ban the use of some antibiotics as growth-promoting agents and advocate for the use of alternatives for disease prevention, including probiotics, better hygiene, and vaccination. Regulations pertaining to AMR are derived from surveillance and data-sharing networks. Probiotics, better cleanliness, and more immunization are some of these strategies.[49]

The origins of AMR regulations may be traced back to monitoring and data-sharing platforms. To track changes in antibiotic usage and resistance, regulatory bodies work with public health institutions, academic institutions, and international databases.[50] The WHO collects new resistance threats among the countries focusing through initiatives such as the GLASS to provide assistance in the response of these countries shown in Table 2. An action plan on AMR entails the real-time monitoring of antibiotic use in hospitals and communities, auditing of prescriptions for antibiotic use, and mandatory reporting of cases of resistance. Regulatory authorities will, therefore, be able to forecast changes in resistance patterns and potentially set up early warning systems to control outbreaks of AMR. The application of AMR should have been a lot easier; however, due to weak enforcement, differences in national regulatory capacities, and a lack of international cooperation, it continues to face challenges. Low and middle-income countries lack adequate regulatory frameworks and scarce resources that hinder the full implementation of AMR policies.[51] International collaboration is critical for closing those gaps by providing financial resources, technical assistance, and capacity-building programs for strengthening regulatory frameworks in resource-poor settings. Governments, regulatory agencies, the pharmaceutical

industry, and international health organizations can act together to harmonize the AMR policy, which will ensure that all nations adopt uniform recommendations for antimicrobial use and resistance control.

LONG-TERM STRATEGIES FOR RESPONSIBLE ANTIMICROBIAL USE

Evidence-based prescribing guidelines

Antimicrobials are prescribed only when necessary because of the development and enforcement of strict prescription guidelines. The recommendations are based on clinical evidence that helps clinicians choose. Appropriate antibiotic, dose, and duration. Countries and state regulatory authorities, the WHO, and the Centers for Disease Control and Prevention (CDC) develop guidelines for the purposes of abuse and misuse. Decision-support systems and electronic prescription systems guide practitioners in making decisions. Evidence-based guidelines reduce unnecessary prescription of antibiotics, hence delaying the spread of resistant bacteria to ensure the long-term effectiveness of antimicrobials in treating the illness.[67]

Surveillance and monitoring systems

Monitoring arms of the antibiotic surveillance system collect information on antibiotic usage patterns, resistance, and treatment outcomes: A valuable asset to policymakers. Such emergence of resistance by country and region is being tracked by regional programs such as WHO's GLASS. National and regional hospitals have conducted audits of antimicrobial use at their hospitals and clinics to ensure compliance with stewardship guidelines. Improving predictions regarding resistance patterns will result from AI and big data analytics through early intervention. Governments and health care take targeted action to combat resistance and limit the growth of multidrug-resistant infections by constantly monitoring trends in AMR.[68]

Public awareness and education campaigns

Public education on AMR should therefore be the major tool for disease prevention through the reduction of self-medication and unneeded medicines. Campaigns, including WHO's World AMR awareness week and the CDC's "Get Smart About Antibiotics" week, as well as India's Red Line Campaign, have made the public aware of the hazards of abuse of antibiotics. Educational resources are distributed via digital platforms, community programs, and schools to promote the proper use of these drugs. Continuous medical education for healthcare professionals guarantees that they are kept aware of changing AMR considerations and appropriate prescribing practices shown in Figure 2. Awareness campaigns will help the public make sound healthcare decisions, which in turn will have an effect on curbing AMR.[69]

Regulation of antimicrobial use in agriculture

Heavy doses of antibiotics in agriculture and livestock make the environment conducive to resistant bacteria. Nations such as the UK, Germany, and Australia impose strict regulations on the utilization of veterinary antibiotics, preventing the inclusion of medically vital antibiotics in growth promotion. U.S. FDA's Guidance for Industry #213 regulates the distribution of antibiotics for purposes other than therapeutic ones. Probiotics, vaccines, and better husbandry practices are sustainable alternatives to reduce the need for antibiotics. In countries that limit antibiotic use in food production, the risk of AMR is reduced significantly.[70]

Investment in R&D

For combating AMR, new antibiotics, along with alternative medicine and rapid diagnostic techniques, are needed. Governments, commercial pharmaceutical industries, and academic institutes finance innovative programs for the future discovery of next-generation antibiotics and non-antibiotic treatments such as phage therapy and immune-based medicines. Research support in antibiotic resistance, such as the Deutsche Forschungsgemeinschaft AMR Research Fund in Germany and the Global Antibiotic R&D Partnership are taking research on antibiotic-resistant infections to the next stage. Rapid testing allows accurate identification of illness and the consequent reduction in unnecessary antibiotic prescribing. Increased AMR-research funding ensures that alternative effective treatment options are always available and averts depletion of effective antimicrobials in health care and agriculture.[71]

SURVEILLANCE SYSTEMS FOR AMR MONITORING

GLASS

The establishment of the GLASS took place in 2015 with the introduction of the WHO's first global AMR surveillance program. It collects information on the therapeutic outcomes, resistance trends, and antimicrobial usage from member countries that report their data to the program. GLASS will help countries develop evidence-based, informative policies by defining harmonized approaches to laboratory testing, data performance, and reporting. It will help co-benefit countries in international cooperation in analyzing resistance patterns, identifying new threats, and coordinating response actions shown in Figure 3. More than 100 countries joined GLASS, which is an instrument for global monitoring of AMR.[72]

National AMR monitoring system (NARMS, USA)

Supervised by the CDC, FDA, and USDA, the NARMS is a monitoring program in the United States (US) that

follows the prevalence of antibiotic resistance in foodborne microorganisms, especially those found in retail meats, food animals, and humans. NARMS shows trends in *Salmonella*, *Campylobacter*, *Escherichia coli*, and *Enterococcus* to evaluate the effects of agricultural antibiotic use on human health. Program data influence public health initiatives, veterinary antibiotic legislation, and food safety activities. The One Health approach against antibiotic resistance incorporates NARMS. Hence, it bridges the environmental, animal, and human AMR concepts.[73]

European AMR surveillance network (EARS-Net)

The European Centre for Disease Prevention and Control is in charge of EARS-Net, which is short for EARS-Net. EARS-Net follows AMR trends in 30 European countries. EARS-Net collects clinical data from hospital laboratories, particularly focusing on resistant bacteria such as methicillin-resistant *Staphylococcus aureus*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*. The system allows early identification of resistance trends in order to help European countries to improve infection control regulation, change antibiotic regimens, and allocate resources correctly. EARS-Net is crucial for guiding plans of action against AMR in the European (EU), as well as for facilitating collaboration among countries in the area of global antimicrobial stewardship.[74]

Indian national AMR surveillance network (NARS-Net)

The NARS-Net was established by the Indian Council of Medical Research to monitor antibiotic resistance in reference laboratories and tertiary care hospitals across the nation. It aids in the formulation of national treatment guidelines by delineating drug-resistant bacteria existing in human infections. In addressing AMR from a One Health approach, NARS-Net considers veterinary and environmental information. The network also supports infection control and antimicrobial stewardship as part of India's national action plan on AMR shown in Figure 4. An immediate priority to enhance India's response to AMR is the extension of NARS-Net's coverage and strengthening laboratory capacity.[75]

Canadian AMR surveillance system (CARSS)

Established by PHAC in 2003, the CARSS serves as a comprehensive database containing AMR data across the national surveillance programs. With a view to integrating detailed information regarding antibiotic use and trends of resistance following the pathway of resistance in veterinary medicine, the human health sector, and food production, it provides CARSS with information from other programs such as the Canadian Integrated Program for AMR Surveillance. They are included in CARSS by evidence-based policy formulation and support the adoption by Canada of successful AMR control policies and antibiotic stewardship programs across sectors.[76]

DEVELOPING THE ONE HEALTH APPROACH IN UPCOMING AMR CONTROL AND RISK MANAGEMENT PLANS

The One Health approach recognizes that environmental, animal, and human health all play a vital role in the management of AMR. Mitigation efforts must be progressively integrated into healthcare, veterinary practices, agriculture, and environmental management for a sustainable and productive global response toward the future of AMR.[76] Enhancing surveillance, enforcing legislation, putting money into research, and international collaboration all need to be part of boosting One Health efforts to avert the development and spread of resistant infections.[77] During the past century, the One Health paradigm has been developed owing to the interdependence of environmental, animal, and human health. The first mention of "zoonosis" goes back to the 19th century, when a German pathologist and physician, Rudolf Virchow, noted that diseases are transmissible from animals to humans. This theory was further developed in the 20th century by veterinarians and medical experts who studied zoonotic diseases such as rabies, tuberculosis, and brucellosis. A precursor of the One Health concept emerged during the 1960s and 1970s when epidemiologists started studying ecological factors affecting disease transmission. However, it was not recognized internationally until the early 2000s.[78] Integrated approaches toward human health, veterinary sciences, and environmental management became necessary due to the outbreaks of SARS in 2003, avian influenza in 2005, and H1N1 in 2009. The worldwide acceptance of the One Health concept was ushered in in 2008 with endorsements from the Food and Agriculture Organization (FAO), World Health Organization (WHO) and World Organisation for Animal Health (WOAH, formerly OIE). The One Health framework has evolved significantly since its inception. In the effort to avert and control newly emerging infectious diseases, governments, academics, and policymakers have incorporated it into several health interventions.[79]

The tripartite collaboration between WHO, FAO, and OIE was further strengthened in 2010 for global health security. Countries began integrating One Health concepts into their national disease surveillance programs, especially for zoonotic diseases like COVID-19, Middle East respiratory syndrome (MERS), and Ebola. Not just limited to infectious diseases, in the last years, topics such as AMR, food safety, climate change, and biodiversity conservation have been included on the One Health agenda. Interdisciplinary research efforts are now aimed at the nexus of epidemics among humans and wildlife commerce and deforestation. The environment

Table 1: Implemented strategies and outcomes in combating AMR by international and national organizations[21-30]

S. No.	Antimicrobial agent	Resistance issue	Regulation by industries and regulatory bodies	Strategies used	Impact
1.	Penicillin	Resistance in *Streptococcus* spp.	WHO, FDA, EMA, Indian CDSCO	Restricted use, alternative antibiotics	Reduced resistance in developed nations
2.	Methicillin	MRSA	CDC, WHO, EUCAST, US FDA	Hospital infection control, surveillance	Decline in hospital-acquired MRSA
3.	Vancomycin	VRSA and VRE	CDC, EMA, WHO, Indian NCDC	Limited use, combination therapies	Some decline in VRSA, ongoing VRE cases
4.	Ciprofloxacin	Fluoroquinolone-resistant *E. coli*	US FDA, WHO, Indian DCGI	Restricted veterinary use	Reduced resistance in certain regions
5.	Tetracycline	Resistance in Gram-negative bacteria	FAO, WHO, EMA, Indian FSSAI	Banned as a growth promoter in livestock	Decreased resistance in foodborne pathogens
6.	Erythromycin	Macrolide-resistant *Streptococcus* and *Staphylococcus*	WHO, CDC, EUCAST	Monitoring, alternative therapies	Mixed impact, resistance persists
7.	Gentamicin	Aminoglycoside-resistant *Klebsiella*	WHO, FDA, EMA	Hospital-based stewardship programs	Partial success, some resistance remains
8.	Rifampin	Resistance in *Mycobacterium tuberculosis*	WHO, Indian RNTCP, US CDC	DOTS therapy, controlled TB treatment	Improved TB control, but MDR-TB remains
9.	Colistin	Resistance in Enterobacteriaceae (*MCR*-1 gene)	WHO, EU EMA, US FDA, Indian ICMR	Banned in food animals, last-resort drug	Declining use, but resistance is still a concern
10.	Linezolid	Oxazolidinone-resistant *Enterococcus*	WHO, US FDA, EMA	Limited prescription, combination therapy	Slowed resistance growth
11.	Clindamycin	Resistance in *Staphylococcus* and anaerobes	WHO, CDC, Indian IPC	Restricted use, alternative antibiotics	Some reduction in resistance
12.	Trimethoprim–Sulfamethoxazole	Resistance in UTI-causing *E. coli*	WHO, EMA, US FDA	Surveillance, alternative prescribing	Moderate resistance decline
13.	Meropenem	CRE	WHO, US CDC, Indian NCDC	ASPs, rapid diagnostics	Limited success due to global spread
14.	Azithromycin	Resistance in respiratory pathogens	WHO, US FDA, EMA	Monitoring in respiratory infections	Increasing resistance trend
15.	Daptomycin	Resistance in Gram-positive bacteria	WHO, US FDA, EMA	Reserved for last-line use	Resistance remains low

AMR: Antimicrobial resistance, WHO: World Health Organization, US: United States, FDA: Food and Drug Administration, EMA: European Medicines Agency, MRSA: Methicillin-resistant *Staphylococcus aureus*, CDSCO: Central Drugs Standard Control Organisation, CDC: Centers for Disease Control and Prevention, EUCAST: European Committee on Antimicrobial Susceptibility Testing, VRSA: Vancomycin-resistant *Staphylococcus aureus*, VRE: Vancomycin-resistant *Enterococcus*, DCGI: Drugs Controller General of India, FSSAI: Food Safety and Standards Authority of India, FAO: Food and Agriculture Organization, EUCAST: European Committee on Antimicrobial Susceptibility Testing, RNTCP: Revised National Tuberculosis Control Programme, MDR-TB: Multi-drug resistant tuberculosis, TB: Tuberculosis, DOTS: Directly observed treatment, short-course, ICMR: Indian Council of Medical Research, IPC: Infection Prevention and Control, CRE: Carbapenem-resistant enterobacteriaceae, UTI: Urinary tract infection, *E. coli*: *Escherichia coli*, NCDC: National Centre for Disease Control

Table 2: Comparative overview of ASP across different countries[52-66]

S. No.	Countries	ASP strategy	Role	Implementation level	Impact on AMR reduction
1.	India	NAP-AMR	Focuses on surveillance, IPC, and rational antibiotic use	Nationwide	Moderate impact due to infrastructure challenges
2.	USA	CDC core elements of hospital ASP	Hospital-based ASPs, stewardship guidelines, and mandatory reporting	Federal and state levels	Significant reduction in antibiotic misuse
3.	UK	Start smart–then focus	Encourages optimal antibiotic prescribing and de-escalation	NHS hospitals and primary care	Effective in reducing broad-spectrum antibiotic use
4.	Germany	ABS initiative	Physician training programs, antibiotic audits, and hospital ASPs	Healthcare institutions	High compliance and reduced antibiotic resistance
5.	Australia	National antimicrobial resistance strategy	Restricts antibiotic use in livestock, promotes ASPs in healthcare	National and state levels	Effective in lowering resistance in both human and animal health
6.	Canada	CARSS	Monitors antibiotic use in humans and animals, supports ASPs	Federal, provincial, and territorial levels	Positive impact on antibiotic prescribing trends
7.	France	Antibiotics only if necessary campaign	Public awareness, physician education, and prescription guidelines	Nationwide public health initiative	Improved public awareness and lower antibiotic consumption
8.	Japan	JANIS	Focus on hospital-based infection control and antibiotic use	Major hospitals	Gradual improvement in AMR trends
9.	China	National ASP and antimicrobial use policy	Bans unnecessary antibiotic prescriptions, hospital ASPs	Nationwide regulation	Significant reduction in hospital antibiotic overuse
10.	Brazil	National program for infection control and ASP	Focuses on reducing hospital-acquired infections and AMR	Public and private healthcare	Moderate impact with room for further improvement
11.	South Africa	South African National ASP framework	Focuses on ASPs in hospitals and community settings	Government-led initiatives	Progress in antibiotic stewardship, but challenges in rural areas
12.	Sweden	STRAMA	Comprehensive ASP with strong surveillance and restriction policies	National and regional levels	One of the lowest AMR rates in the world
13.	The Netherlands	SWAB (Dutch working party on antibiotic policy)	Strict antibiotic guidelines, low antibiotic use	Nationwide enforcement	Highly successful in controlling antibiotic resistance
14.	Russia	National strategy for AMR control	Regulations for antibiotic use in healthcare and agriculture	Government-led but limited enforcement	Mixed results due to varying compliance levels
15.	Thailand	Thailand's National Strategic Plan on AMR	Promotes ASPs in hospitals, surveillance, and public education	Nationwide initiative	Effective in reducing antibiotic misuse in healthcare settings

IPC: Infection Prevention and Control, CDC: Centers for Disease Control and Prevention, ASP: Antimicrobial stewardship programs, NHS: National Healthcare Safety Network, NAP-AMR, National action plan on antimicrobial resistance, ABS: Antibiotic stewardship, JANIS: Japan nosocomial infections surveillance, STRAMA: Strategic program against antimicrobial resistance, CARSS: Canadian antimicrobial resistance surveillance system

enhancement of the framework occurred in 2021 after the United Nations Environment Programme (UNEP) became a member of the One Health High-Level Expert Panel.[80] One Health European Joint Programme (OHEJP) and Global One Health Initiative (GOHI) also contributed their shares to research, policy integration, and capacity building for One Health. The human health surveillance network was then made up of One Health concept, almost efficiently,

recently with such zoonotic diseases as COVID-19, MERS, or Ebola. In addition, not infectious diseases, in recent years, there have been a lot in the last decades added to the One Health agenda: AMR, food safety, climate change, and biodiversity conservation. The newest intersection concerning subject matter for interdisciplinary research is human disease epidemics' connection to wildlife commerce and deforestation. In 2021, the environmental component of the framework was strengthened by the entry of the UNEP within the One Health High-Level Expert Panel. OHEJP and GOHI also contributed to One Health research, policy integration, and capacity-building efforts.[81] These days, countries are beginning to imbibe the One Health concept into their national disease surveillance programs, especially in the case of zoonotic diseases such as COVID-19, MERS, and Ebola. Beyond infectious diseases, AMR, food safety, climate change, and conservation of biodiversity, the One Health agenda has also added on over the years. Now interdisciplinary research efforts are aimed toward the nexus of human disease epidemics with the two next topics: Wildlife commerce and deforestation. In 2021, the UNEP was accepted as a member of the One Health High-Level Expert Panel, thereby strengthening the environmental component of the framework. One Health research, policy integration, and capacity building have also been covered by the OHEJP and the GOHI.[82] The future of One Health will depend on technological innovation, better global governance, and interdisciplinary research. AI-driven disease modeling and genomic surveillance in real-time will allow early detection and responses to new threats.[83] Zoonotic disease vaccines and diagnostic tools will be expedited through partnerships between the public and private sectors. As more nations are expected to integrate the One Health framework into their national action plans, this will necessitate maintaining some degree of integrated policy. Increased funding is required for One Health education and workforce development to train health, veterinary, and environmental professionals in joint disease management. Future pandemic threats will also be mitigated through wildlife protection schemes and sustainable land-use policies.[84]

CONCLUSION

AMR poses a challenge to the entire world, threatening the economies, food security, and health of people everywhere. This accounts for the contents of the book, wherein projects driven by industry and standardized regulatory frameworks advocate for the urgent need to contain AMR through strict legislation, state-of-the-art technologies, and environmentally friendly practices. The need to develop integrated AMR control and risk management plans calls for collaborative actions across governments, healthcare systems, pharmaceutical industries, and agriculture sectors under the One Health model of intervention. Industry compliance with regulatory bodies is important in controlling AMR. Pharmaceutical companies will conduct their activities with GMPs to avoid environmental contamination, while strict regulatory laws track and limit the use of antibiotics. For example, enhanced waste disposal legislations are being put into place by countries like the EU, the US, and India to prevent contamination from antibiotic leftovers in soils and oceans.

However, impediments, such as a lack of compliance, weak enforcement, and limited infrastructure in the developing world, block the way for progress. Closing such regulatory loopholes will entail international cooperation and the introduction of standardized AMR regulations. ASPs and rigorous surveillance systems are the cornerstones of the proper control of AMR. Resistance-trend tracking has greatly benefited from international programs such as WHO's GLASS, U.S. NARMS, and India's NARS-Net. In contrast, the enhancement of real-time monitoring by genetic sequencing, AI, and machine learning will go a long way toward assisting with early diagnosis and intervention. Digital health technologies, fast diagnostics, and evidence-based prescribing recommendations will enable antibiotic stewardship in facility settings. The extension of ASPs to the veterinary and agricultural sectors will further decrease antibiotic use in food production and prevent the spread of resistance. Sustainable solutions aside, futuristic innovation in science is essential for AMR reduction. Promising next-generation medicines have emerged from research into CRISPR-based bacterial gene editing, antimicrobial peptides, and bacteriophage therapy. Environmental pollution would also be reduced through developing biodegradable antibiotics, stricter pharmaceutical waste management regulations, and environmentally friendly antibiotic production techniques. Governments must use those financing channels, public–private partnerships, and policy-driven financial support to encourage pharmaceutical firms to participate in R&D linked to AMR. One Health integrates environmental, animal, and human health toward a sustainable AMR strategy. Future AMR control will incorporate all aspects of global disease surveillance, food safety laws, climate action, and biodiversity preservation. Then, run by the international legislative frameworks, AI-driven surveillance, and digital health technologies, all global AMR programs will become more efficient. Innovation in science and sustainable solutions will be the future of AMR reduction.

Research into CRISPR-based bacterial gene editing, antimicrobial peptides, and phage therapy gave promise to the developing next-generation medicines. Pollution of the environment is also curtailed through the development of biodegradable antibiotics, mandatory stricter pharmaceutical waste management regulations, and environmentally safe processes for antibiotic production. Governments must develop financing channels, adopt public–private partnerships, and implement policy-driven financial support to encourage pharmaceutical firms to involve themselves actively in R&D related to AMR. Topmost on the list of priorities among policymakers should be research and

educational programs concerning AMR to influence the general public and health care professionals on appropriate antibiotic use. Last but not least, an integrated approach through government regulation, industry best practice, and collaboration would be the only way for successful AMR management. Preventing contamination and the development of resistant strains can be achieved by strengthening regulatory regulations linked to policies on the manufacturing of antibiotics in accordance with strict quality control processes. To accurately track growth in antibiotic usage and resistance, regulatory agencies must also enhance their surveillance techniques. The innovative One Health approach needed for future sustainable AMR actions recognizes the interdependent linkage between all environmental, animal, and human health. Future approaches to AMR control will include all aspects of global disease surveillance, food safety legislation, climate action, and biodiversity conservation. Further, international legislative frameworks, AI-driven surveillance, and digital health technologies will drive the efficacy of all global AMR programs.

AUTHOR'S CONTRIBUTION

M. P. Murali Krishnan: Reviewed, edited, and refined the intellectual content. All authors approved the final version and agreed to accountability for the work. Supervised the research design and finalized the manuscript. Saravanan Ravindran: Contributed to conceptualization, literature synthesis, and initial drafting, performed formal analysis of included studies and critical evaluation, resource curation, and data validation.

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