WHO

STUDY GUIDE

Topic 1: Addressing the Growing Threat of Antimicrobial Resistance (AMR)

Topic 2: Establishing a Global Framework for the Regulation and Trafficking of Genome-Edited Products

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1. LETTER FROM THE CHAIRS

Dear Delegates,
As chairs of the one and only World Health Organisation, we would like to welcome you to this year's edition of JASMUN! We are extremely honored to have the opportunity to overlook the debates in our committee, and look forward to seeing many fruitful discussions unfold during the conference!
In this Study Guide, you will find information which will help you understand the topics you will be debating upon, as well as preparing your position papers, speeches, and resolutions. We encourage you, however, to use other sources for your research as well, whether they come from our Recommended Reading sections or not.

If you would like to ask about anything regarding anything related to the conference, please don't hesitate to contact us, as it is in our best interest to make this experience as good as we can for everybody!

Best regards,
Tomina Ionescu and Maksymilian Zięć,
Chairs of World Health Organisation.

2. INTRODUCTION TO THE COMMITTEE

The World Health Organization (WHO) is the United Nations specialized agency responsible for international public health. Established in 1948, the WHO works to promote health, prevent and control disease, strengthen health systems, and coordinate international responses to health emergencies. Its Constitution defines its objective as the attainment by all peoples of the highest possible level of health.

The WHO brings together its 194 Member States to develop international health policies, establish standards, provide technical assistance, and coordinate responses to global health challenges.

The work of the WHO is governed primarily through the World Health Assembly, which serves as the Organization's supreme decision-making body. It meets annually and is attended by delegations from all WHO Member States. The Executive Board, composed of 34 technically qualified members, implements the decisions and policies of the Health Assembly and prepares its agenda. The Secretariat, headed by the Director-General, carries out the Organization's day-to-day work.

The work of the Organization currently falls under six objectives:

- Addressing the health impacts of climate change
- Tackling the underlying determinants and root causes of ill health
- Strengthening primary health care and universal health coverage
- Improving health service coverage and financial protection
- Preventing and preparing for health risks and emergencies
- Detecting and responding rapidly to health emergencies

3. TOPIC 1

Addressing the Growing Threat of Antimicrobial Resistance (AMR)

3.1 Introduction to the topic

Antimicrobial Resistance, by definition, occurs when microorganisms evolve mechanisms allowing them to survive exposure to medicines that would normally kill them or inhibit their growth. Microorganisms involved in that process include bacteria, viruses, fungi, and parasites. Although AMR itself is an umbrella term, it is currently mainly used to represent antibiotic resistance, which occurs specifically in bacteria.

AMR is fundamentally a biological evolutionary process, during which microorganisms naturally mutate and evolve. This happens because antimicrobial use creates selection pressure, which causes susceptible organisms to die, and resistant organisms to survive, reproduce, and mutate to resist particular drugs.

What is important is that this resistance can spread, as bacteria are able to exchange genetic material, through a process called horizontal gene transfer.

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What makes this different from a normal infectious-disease problem is that medicines used to treat infections gradually become less effective, threatening some of the foundations of modern medicine.

Besides all that, something worth noting is that AMR threatens not only our ability to treat infections, but the safety of many medical procedures that depend upon effective antimicrobial drugs. But how severe is the issue at hand?

Well, WHO currently reports that one in six laboratory-confirmed bacterial infections causing common infections worldwide in 2023 were resistant to antibiotic treatment. Resistance increased in more than 40% of the pathogen-antibiotic combinations monitored between 2018 and 2022.

WHO also states that approximately 4.71 million deaths were associated with drug-resistant infections, and approximately 1.14 million deaths were directly attributable to bacterial AMR.

Furthermore, approximately 39 million deaths could be directly attributable to AMR between 2025 and 2050 if current trends are not sufficiently reversed.

With that said, it is clear that AMR is already causing deaths and isn't merely a hypothetical future threat (with all due respect to the Future Security Council). Resistance is occurring against antibiotics currently considered essential, and if said resistance increases, it could eventually leave clinicians with.

- fewer treatment options;
- more expensive treatments;
- more toxic treatments;
- longer treatment periods;
- higher mortality.

What doesn't help, and is at the same time one of the main reasons for AMR being a major issue for the WHO, is that Antimicrobial Resistance doesn't affect every country equally. Lower income countries often struggle with higher infectious-disease burdens, weaker healthcare infrastructure, limited diagnostic and laboratory capacity, and you probably get the point by now. What this means is that countries experiencing some of the greatest AMR burdens may simultaneously have the fewest resources available to combat it.

As you may probably notice by now, AMR thus has two seemingly contradictory problems. On one hand we are faced with overuse, more specifically unnecessary antibiotics or inappropriate prescriptions, and on the other hand there is the under-access of health infrastructure, diagnostics, and antibiotics themselves.

The solution to AMR must be achieved through finding an appropriate balance - using antibiotics responsibly while ensuring access for those who need them, and this is a central challenge in WHO's AMR policy. One of the main drivers of AMR is, as was already discussed, the overuse and misuse of antimicrobials. This includes the following:

- antibiotics prescribed for viral infections;
- unnecessary prescriptions;
- incorrect antibiotic choice;
- incorrect dosage;
- unnecessarily long treatment;
- patients self-medicating;
- incomplete or inappropriate use;
- inappropriate use of broad-spectrum antibiotics.

This last point is particularly relevant, as broad-spectrum antibiotics kill a wider range of bacteria. While this might seem useful at first (and in some cases it really is, for instance when the pathogen isn't known), the use of such antibiotics allows a larger amount of bacteria to learn to resist a given treatment, rendering it less effective quicker.

This misuse can be seen well in statistics published by WHO. In 2022, approximately 53% of human antibiotic consumption came from "Access" antibiotics, and approximately 45% came from "Watch" antibiotics. Those terms come from WHO's AWaRe classification, which is quite useful when determining how scarcely a drug should be used to prevent AMR. The classification looks as follows:

- Access: first-choice treatments for many common infections, with relatively low resistance potential.
- Watch: antibiotics with a higher resistance potential that should be used more selectively.
- Reserve: last-resort options, usually intended for infections caused by multidrug-resistant organisms.

Simply put, Access antibiotics should be used first, then Watch, and lastly Reserve, in order to minimise AMR. Following this principle, antimicrobial stewardship becomes one of the most important tools available to governments and healthcare systems. Antimicrobial stewardship essentially means ensuring that antimicrobials are used only when necessary, against the appropriate pathogen, at the appropriate dose, for the appropriate duration, and preferably using the narrowest effective treatment.

In other words, the objective is not simply to use as few antibiotics as possible, but to use them as appropriately as possible. This distinction is particularly important, as overly restrictive policies could delay necessary treatment and worsen the very access problems that contribute to unequal health outcomes. Governments can encourage antimicrobial stewardship through prescription requirements, national prescribing guidelines, hospital stewardship programmes, monitoring of antimicrobial consumption, pharmacist involvement, restrictions on certain antibiotics, education for healthcare workers, and electronic prescription systems. Hospitals can also conduct regular audits of prescribing practices and provide feedback to physicians.

The underlying principle is relatively simple: every unnecessary dose of an antimicrobial creates additional selection pressure, while every appropriate dose provides a necessary medical benefit. However, reducing the need for antimicrobials in the first place is arguably even more effective. Infection prevention and control therefore represents another fundamental component of the global response to AMR. If fewer people become infected, fewer people require antimicrobial treatment, which consequently reduces the opportunities for resistant microorganisms to emerge and spread. Measures such as hand hygiene, vaccination, sterilisation, safe surgical procedures, isolation of infected patients, appropriate use of personal protective equipment, and effective hospital infection-control protocols can therefore indirectly reduce AMR.

This is particularly relevant when considering WASH, meaning Water, Sanitation and Hygiene. Inadequate access to clean water, sanitation, hygiene and wastewater treatment facilitates the transmission of infectious diseases. More infections mean greater demand for antimicrobial treatment, which creates greater selection pressure for resistance. This is particularly relevant when considering WASH, meaning Water, Sanitation and Hygiene. Inadequate access to clean water, sanitation, hygiene and wastewater treatment facilitates the transmission of infectious diseases. More infections mean greater demand for antimicrobial treatment, which creates greater selection pressure for resistance. At this point, however, it is important to recognise that AMR does not remain confined to hospitals or even to human healthcare. Resistant microorganisms can move between humans, animals and the environment, which is why AMR is increasingly approached through what is known as the One Health framework.

One Health is based on the understanding that the health of humans, animals, plants and the environment is interconnected. Consequently, antimicrobial use in one sector can have consequences in another. For example, an antibiotic may be administered to livestock, creating selection pressure that favours resistant bacteria. These bacteria can then spread between animals or contaminate food, soil or water. Humans can subsequently be exposed to these organisms and develop infections that are more difficult to treat. For example, an antibiotic may be administered to livestock, creating selection pressure that favours resistant bacteria. These bacteria can then spread between animals or contaminate food, soil or water. Humans can subsequently be exposed to these organisms and develop infections that are more difficult to treat. This is why four international organisations work together through the Quadripartite framework on AMR: the World Health Organization, the Food and Agriculture Organization of the United Nations, the United Nations Environment Programme, and the World Organisation for Animal Health.

Their cooperation reflects the fact that no single sector can adequately address AMR independently. Their cooperation reflects the fact that no single sector can adequately address AMR independently. For WHO Member States, this means that an effective response cannot focus exclusively on hospitals while ignoring veterinary medicine, agriculture, food systems or environmental pollution. The problem arises when antimicrobials are unnecessarily or inappropriately used, including where poor farm management or inadequate biosecurity creates a need for medicines that could otherwise have been prevented.

Governments can reduce this demand through vaccination, improved animal nutrition, better housing, stronger biosecurity, veterinary oversight, disease surveillance and improved farm management. Governments can reduce this demand through vaccination, improved animal nutrition, better housing, stronger biosecurity, veterinary oversight, disease surveillance and improved farm management. The objective should therefore not be to prevent farmers from treating sick animals, but to reduce the number of infections requiring treatment in the first place.

This is important not only for AMR but also for food security. Resistant infections can increase animal mortality, reduce productivity, increase veterinary and production costs and ultimately contribute to higher food prices and reduced food availability.

The environmental dimension of AMR is another area that has become increasingly important. Resistant organisms and antimicrobial residues can enter the environment through hospital and municipal wastewater, livestock farms, aquaculture, agricultural runoff, sewage, improperly disposed medicines and pharmaceutical manufacturing.

Of particular concern is the release of active pharmaceutical ingredients from antibiotic production facilities. Where sufficiently high concentrations of antibiotics enter wastewater, they can create environmental conditions that favour the survival of resistant microorganisms. This introduces an additional pathway through which AMR can develop and spread: pharmaceutical manufacturer > wastewater > environment > microorganisms > humans or animals. Addressing this pathway may require stronger wastewater treatment, environmental discharge standards, monitoring of antimicrobial concentrations, responsible disposal practices and greater transparency within pharmaceutical supply chains.

At the same time, governments must consider the economic consequences of such regulation. Stricter environmental requirements could increase manufacturing costs and potentially affect the affordability and availability of medicines. This creates another policy dilemma: how can governments reduce pharmaceutical pollution without making essential medicines less accessible?

The ability to understand these problems also depends heavily on surveillance. Countries cannot effectively combat AMR if they do not know which pathogens are resistant, where resistance is occurring, how rapidly it is increasing, which antimicrobials are being used, or how resistant organisms are moving between humans, animals and the environment.

This is why international data collection is so important. WHO's Global Antimicrobial Resistance and Use Surveillance System (GLASS) aims to standardise the collection and reporting of AMR and antimicrobial-use data, allowing countries to monitor trends and allowing the international community to identify emerging threats.

However, surveillance capacity is extremely unequal. Some countries continue to face shortages of microbiology laboratories, trained personnel, diagnostic equipment, reliable health records and funding. This creates a particularly problematic situation in which countries with potentially significant AMR burdens may also have the least reliable data about those burdens. Strengthening surveillance therefore requires more than simply asking countries to submit more statistics. Governments may need to establish national surveillance networks, expand microbiological laboratories, train healthcare and laboratory personnel, standardise diagnostic procedures, digitise health records and improve reporting systems. Ideally, human, veterinary and environmental surveillance should also become increasingly interconnected, allowing governments to identify resistance patterns across the entire One Health system.

Surveillance, however, is only useful if countries have the ability to identify infections in the first place. This makes diagnostics another crucial component of the AMR response.

In many situations, doctors must prescribe treatment before knowing exactly which microorganism is responsible for an infection or whether that microorganism is resistant to a particular drug. As a result, clinicians may prescribe antibiotics unnecessarily, choose broad-spectrum antibiotics as a precaution, or select a treatment that ultimately proves ineffective. Rapid diagnostic technologies could significantly reduce this problem by allowing healthcare workers to determine whether an infection is bacterial or viral, identify the pathogen responsible, determine whether resistance is present, and select the most appropriate treatment. This is particularly important in primary care, emergency departments, rural healthcare facilities, low-income countries and humanitarian settings, where laboratory infrastructure may be limited.

The international community should therefore not focus exclusively on expensive, highly specialised laboratories. There is also a need for affordable, rapid, portable and easy-to-use point-of-care diagnostic technologies.

Expanding access to such technologies could simultaneously improve patient outcomes and reduce inappropriate antimicrobial use. This is reflected in the 2024 UN Political Declaration, which established a target for at least 80% of countries to have the capacity to test resistance in key GLASS bacterial and fungal pathogens by 2030. Even with stronger prevention, stewardship, diagnostics and surveillance, however, resistance will continue to emerge. This makes research and development another essential part of the international response. Even with stronger prevention, stewardship, diagnostics and surveillance, however, resistance will continue to emerge. This makes research and development another essential part of the international response.

This creates a fundamental contradiction: the antibiotic that society most urgently needs may be the antibiotic that society wants doctors to use the least. Consequently, pharmaceutical companies may face high research and development costs while simultaneously facing an intentionally limited market for their final product. Additional problems include expensive clinical trials, high rates of failure, long development timelines and competition from inexpensive generic antibiotics. The current pipeline illustrates this challenge. WHO reported in 2025 that 90 antibacterial products were in clinical development as of February 2025, including 50 antibiotics and 40 non-traditional antibacterial products.

However, relatively few of these products target the highest-priority resistant pathogens, and even fewer meet WHO's criteria for meaningful innovation. At the preclinical stage, 232 antibacterial therapeutics were being developed, with approximately 94% originating from high-income countries. This highlights not only the scientific challenge of developing new treatments, but also the geographical concentration of AMR research and development. Innovation should not necessarily mean simply producing another antibiotic. Potential approaches include new antibiotic classes and mechanisms of action, bacteriophages, monoclonal antibodies, vaccines, microbiome-based therapies and anti-virulence treatments.

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Push incentives provide financial support during the research and development process. These can include grants, subsidies, public research funding, tax incentives and public-private partnerships. Their purpose is to reduce the cost and financial risk associated with developing new treatments.

Pull incentives operate differently. Rather than reducing development costs, they reward successful innovation after a product has been developed. Examples include market-entry rewards, guaranteed purchasing, advance purchase commitments, milestone payments and subscription models.

A subscription model is particularly interesting in the context of AMR because a government can pay a pharmaceutical company a fixed amount for access to an antibiotic rather than paying according to the number of doses sold.

This can provide companies with a predictable source of revenue without creating an incentive to maximise antibiotic consumption. However, developing a new antimicrobial means little if patients who need it cannot actually obtain it. This brings us to another central paradox of AMR: the world must simultaneously reduce unnecessary antimicrobial consumption and increase access to antimicrobials for people who genuinely need them.

In many low- and middle-income countries, barriers to access can include high prices, medicine shortages, weak supply chains, inadequate healthcare infrastructure, geographical isolation and limited diagnostic capacity. Even when a new antibiotic is successfully developed, governments must therefore consider who will receive it, who will pay for it, how it will be distributed and whether poorer countries will be able to access it at an affordable price.

Possible solutions include tiered pricing, pooled procurement, international financing, technology transfer, licensing agreements, regional stockpiles and international purchasing mechanisms. Possible solutions include tiered pricing, pooled procurement, international financing, technology transfer, licensing agreements, regional stockpiles and international purchasing mechanisms. The consequences of AMR also extend far beyond hospitals. Resistant infections can require longer hospital stays, more expensive medicines, additional diagnostic testing, more complicated procedures and intensive care. Treatment failures can also increase mortality and place additional pressure on already limited healthcare resources.

There are also broader economic consequences. Patients suffering from resistant infections may miss school or work, become temporarily or permanently unable to work, or require long-term care. Employers experience lost productivity, while governments and healthcare systems face additional expenditure. Across 34 OECD and EU/EEA countries, AMR has been estimated to cost approximately US$66 billion in purchasing-power-parity terms every year, including around US$28.9 billion in health-system costs and US$36.9 billion in wider economic costs. Agriculture faces similar consequences. Resistant infections can increase animal mortality, reduce productivity, increase veterinary expenses and raise the costs of food production.

AMR can therefore undermine food security as well as public health, making it relevant not only to SDG 3, Good Health and Well-being, but also to SDG 2, Zero Hunger; SDG 6, Clean Water and Sanitation; SDG 8, Decent Work and Economic Growth; SDG 12, Responsible Consumption and Production; and SDG 17, Partnerships for the Goals. All of these consequences demonstrate why AMR cannot realistically be solved by individual countries acting alone. Resistant microorganisms do not respect national borders. They can spread through international travel, migration, food and livestock trade, agricultural products, pharmaceutical supply chains, wastewater and environmental transmission.

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A resistant pathogen emerging in one country can therefore reach another country through travel and subsequently spread through hospitals or communities. This is why international cooperation has been a central component of the global AMR response. The original WHO Global Action Plan on Antimicrobial Resistance, adopted in 2015, established five major objectives:

- improving awareness and understanding of AMR;
- strengthening surveillance and research;
- reducing the incidence of infection;
- optimising antimicrobial use;
- developing the economic case for sustainable investment in new medicines, diagnostics, vaccines and other interventions.

The international framework was further strengthened in September 2024, when United Nations Member States adopted a Political Declaration on AMR. The declaration established a number of targets for 2030, including a 10% reduction in deaths associated with bacterial AMR compared with the 2019 baseline, at least 70% of human antibiotic consumption coming from the WHO Access group, improved national surveillance capacity, universal basic WASH services in healthcare facilities, stronger infection-prevention and control systems, and reductions in inappropriate antimicrobial use within agrifood systems.

The declaration also called for US$100 million in catalytic funding by 2030, with the objective of helping at least 60% of countries establish funded national AMR action plans. These commitments are particularly useful for policymakers because they provide existing international targets that countries can build upon rather than creating entirely new objectives from scratch.

However, as the international community entered 2026, the response to AMR itself entered a new phase. In May 2026, the 79th World Health Assembly adopted the updated WHO Global Action Plan on Antimicrobial Resistance for 2026–2036. Developed through cooperation between WHO, FAO, UNEP and WOAH, the updated framework seeks to reduce bacterial AMR-associated deaths, reduce inappropriate antimicrobial use in agrifood systems, minimise environmental pollution from antimicrobial residues and resistant microorganisms, and strengthen One Health cooperation.

The updated framework places particular emphasis on awareness and behavioural change, prevention and infection reduction, surveillance and evidence, access and appropriate antimicrobial use, research and innovation with sustainable financing, and governance, coordination and accountability. For this committee, this is particularly significant because Member States are no longer debating AMR in a policy vacuum. Instead, the question becomes how the international community can effectively implement, finance, strengthen and operationalise the commitments established under this new framework.

Nevertheless, these frameworks do not eliminate the difficult political choices surrounding AMR. In fact, some of the most important questions facing WHO involve balancing competing objectives. The first is access versus stewardship. Governments need to reduce unnecessary antibiotic consumption while ensuring that patients who genuinely require antibiotics can obtain them. If prescription controls are too weak, misuse may accelerate resistance; if they are too restrictive, patients may be denied essential treatment.

The second is innovation versus conservation. The world needs new antibiotics and other antimicrobial technologies, but these products must then be protected from overuse in order to preserve their effectiveness. Governments must therefore determine how pharmaceutical companies can be financially rewarded without creating incentives to sell as many doses as possible.

The third is regulation versus affordability. Stronger environmental standards could reduce pharmaceutical pollution and environmental selection pressure, but they may also increase manufacturing costs. Governments must therefore consider who should bear these costs and whether stricter standards could ultimately affect medicine prices or supply. The fourth is global standards versus national sovereignty. Internationally coordinated standards can make the global response more effective, but countries have very different healthcare systems, financial capabilities and levels of AMR.

A standard that is realistic for a high-income country may be considerably more difficult for a low-income country to implement. This raises the question of whether international requirements should be binding or primarily voluntary, and how wealthier countries should support those with fewer resources. The fifth is agriculture versus public health. Farmers need access to antimicrobials to treat sick animals, but inappropriate use in agriculture can contribute to resistance.

Governments therefore face difficult questions concerning prophylactic use, veterinary prescriptions, antimicrobial restrictions and financial assistance for farmers transitioning towards lower-antimicrobial production systems. The sixth is data sharing versus national capacity. International surveillance requires countries to collect and share reliable data, yet some states lack the laboratories, personnel and infrastructure necessary to do so. Simply demanding more reporting without providing the resources required to collect the data could therefore disproportionately disadvantage countries already facing the greatest challenges.

Finally, there is the question of prevention versus treatment. Governments have limited resources and must determine how much should be invested in preventing infections through vaccination, WASH, hygiene and infection control, compared with developing new treatments for infections that have already become resistant. In reality, neither approach can replace the other. A successful global strategy must reduce the emergence and transmission of resistance while simultaneously ensuring that effective treatments remain available.

The way forward therefore requires action across multiple areas at once. Governments can strengthen prevention through vaccination, WASH, hygiene, infection prevention and hospital infection-control programmes.

They can improve responsible antimicrobial use through stewardship programmes, AWaRe-based prescribing, healthcare-worker training and veterinary prescribing rules. They can strengthen surveillance through GLASS and national AMR networks, while integrating human, animal and environmental data.

They can also expand access to rapid and affordable diagnostics, invest in agricultural biosecurity and animal vaccination, establish stronger environmental standards for wastewater and pharmaceutical manufacturing, and create economic incentives for antimicrobial research and development.

At the international level, this can be supported through financing mechanisms, technology transfer, pooled procurement, technical assistance, international reporting and cooperation between WHO, FAO, UNEP and WOAH.

Ultimately, Antimicrobial Resistance is not simply one problem. It is simultaneously a medical problem, because infections are becoming harder to treat; a public-health problem, because healthcare systems face greater pressure; an agricultural problem, because antimicrobial use in animals and food production can contribute to resistance; an environmental problem, because resistant organisms and antimicrobial residues can enter ecosystems; an economic problem, because resistant infections increase healthcare costs and reduce productivity; an innovation problem, because the traditional pharmaceutical market does not provide sufficient incentives for new antimicrobials; an equity problem, because some populations lack both medicines and diagnostics; and an international-governance problem, because resistant microorganisms do not respect national borders.

For this reason, no single ministry, sector, country or organisation can solve AMR independently. The challenge facing the international community is not simply to develop more antibiotics or to tell doctors and farmers to use fewer of them.

It is to construct a system in which infections are prevented whenever possible, antimicrobials are used responsibly when they are necessary, effective treatments remain accessible to those who need them, new treatments continue to be developed, and the emergence and spread of resistance are monitored across humans, animals and the environment.

The central question for the WHO, therefore, is not whether AMR should be addressed, but how the international community can balance these competing priorities while ensuring that antimicrobial medicines remain effective for future generations.

3.2 Case Studies

China

China is one of the most important countries when discussing AMR because of its population, large agricultural sector, healthcare system and pharmaceutical industry. It adopted its first National Action Plan to Contain Antimicrobial Resistance for 2016–2020, followed by a second plan covering 2022–2025. Both plans use a One Health approach, meaning that human healthcare, veterinary medicine, agriculture, environmental protection and pharmaceutical production are considered together rather than separately. China has made substantial progress in reducing antimicrobial use. WHO reports that the proportion of hospital inpatients receiving antimicrobials fell from approximately 59.4% in 2011 to 36% in 2019. The country has also introduced prescription controls, antimicrobial stewardship programmes and measures to reduce inappropriate veterinary antimicrobial use, including restrictions on the use of certain antibiotics as growth promoters.

The pharmaceutical sector creates another important part of the picture. China is one of the world's largest producers of antibiotics and pharmaceutical ingredients, so antimicrobial residues from manufacturing can become an environmental issue. Antibiotics entering wastewater can create selection pressure that favours resistant microorganisms, which is why China has increasingly focused on pharmaceutical wastewater and environmental monitoring as part of its AMR response.

There are, however, considerable differences between regions in healthcare resources, laboratory capacity and implementation. National policies consequently have to be applied across a very large number of hospitals, farms, laboratories and manufacturing facilities. China's experience provides a particularly large-scale example of the practical difficulties involved in implementing a coordinated One Health strategy.

United Kingdom

The United Kingdom has developed a relatively comprehensive approach to AMR through its Confronting Antimicrobial Resistance 2024–2029 strategy. The plan focuses on preventing infections, improving antimicrobial use, supporting innovation and access, and strengthening international cooperation. Vaccination, infection prevention, surveillance and public awareness are therefore treated as important parts of the AMR response rather than as separate health policies.

The UK is also notable for its approach to antibiotic development. New antibiotics are expensive to develop, but once they are available, they need to be used sparingly so that resistance does not develop against them. The UK has attempted to address this through a subscription model in which the NHS pays pharmaceutical companies for access to selected antibiotics based on their value to the healthcare system rather than simply the number of doses sold.

This separates the financial return from the volume of antibiotics prescribed. The UK has consequently become an important example of how antimicrobial stewardship can be incorporated into the economic model surrounding pharmaceutical innovation.

Switzerland

Switzerland adopted its Strategy on Antibiotic Resistance (StAR) in 2015. The strategy covers human and veterinary medicine, agriculture, food production and the environment, with particular attention given to surveillance, prevention, appropriate antimicrobial use, research and international cooperation. Switzerland is especially relevant because of its pharmaceutical industry and research capacity. The country has the resources to contribute to antimicrobial R&D, yet the basic economic problem remains the same: new antibiotics are expensive to develop and are then deliberately used in limited quantities. A strong pharmaceutical sector therefore does not automatically guarantee a strong pipeline of new antibiotics.

Switzerland has participated in international efforts to strengthen AMR research and surveillance while maintaining domestic stewardship programmes. Its experience connects several of the major issues surrounding AMR, particularly pharmaceutical innovation, responsible use and international financing.

Japan

Japan adopted its first National Action Plan on AMR in 2016 and introduced an updated National Action Plan on Antimicrobial Resistance 2023–2027. The strategy covers antimicrobial stewardship, infection prevention, surveillance, research and development, public awareness and international cooperation. Japan has invested substantially in monitoring both resistance and antimicrobial consumption. Its relatively strong healthcare and laboratory infrastructure makes this easier than in many lower-income countries, while measures have also been introduced to reduce inappropriate antimicrobial use in veterinary medicine and agriculture.

Japan's technological and pharmaceutical sectors provide additional capacity for developing diagnostics and new treatments. The country has also raised AMR through international forums including the G7, linking its domestic response with wider international cooperation.

India

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One of the most important features of the Indian situation is that overuse and under-access occur at the same time. In some settings, antibiotics can be obtained without appropriate medical supervision, contributing to unnecessary use. In poorer and rural areas, however, access to qualified healthcare, diagnostics and essential medicines can be limited. This makes antibiotic regulation particularly complicated, since reducing unnecessary consumption cannot come at the expense of people who already struggle to obtain appropriate treatment.

India's pharmaceutical industry adds another layer to the problem. The country is one of the world's largest producers of generic medicines and antibiotics, making affordable pharmaceutical production particularly important. At the same time, antimicrobial residues from pharmaceutical manufacturing can enter wastewater and contribute to environmental selection pressure. The regulation of pharmaceutical pollution therefore has to be considered alongside the importance of maintaining access to affordable medicines.

India has also expanded its AMR surveillance network and participates in GLASS. However, laboratory and diagnostic capacity varies considerably between regions. Where doctors cannot quickly determine which pathogen is responsible for an infection, empirical treatment becomes more likely, including the use of broad-spectrum antibiotics. India's situation consequently brings together several of the central issues surrounding AMR: access to treatment, inappropriate use, diagnostics, pharmaceutical production, environmental pollution and healthcare inequality.

Brazil

Brazil is particularly relevant to the agricultural side of AMR. It is one of the world's largest producers and exporters of agricultural products, meaning that antimicrobial use in livestock and food production can have consequences beyond individual farms. Brazilian AMR policies therefore cover human healthcare as well as veterinary medicine, agriculture and environmental health. Reducing inappropriate antimicrobial use in agriculture has to be balanced with the need to treat sick animals and maintain food production. Brazil has consequently focused on veterinary oversight, surveillance and improving agricultural practices.

The country also has substantial differences in healthcare and laboratory capacity between regions. This affects its ability to identify resistant organisms and monitor antimicrobial consumption, making improvements in diagnostics and surveillance an important part of its wider AMR response.

South Africa

South Africa faces AMR alongside a substantial infectious-disease burden and significant differences in healthcare access between regions. Its National Action Plan focuses on surveillance, infection prevention and control, antimicrobial stewardship, research and public awareness. Diagnostic capacity is particularly important. In rural and underserved areas, access to microbiological testing can be limited, meaning that healthcare workers may have to rely on empirical treatment without knowing the exact pathogen or its resistance profile.

The country's experience with drug-resistant tuberculosis adds another major dimension. Resistant TB can require long and complicated treatment and places significant demands on patients and healthcare systems. South Africa therefore provides an example of how antimicrobial resistance can compound existing infectious-disease challenges.

Netherlands

The Netherlands has developed a strong antimicrobial-stewardship system and maintains relatively low antibiotic consumption. Its approach relies on prescribing guidelines, diagnostic testing, surveillance and close cooperation between physicians, pharmacists and microbiologists.

The same principle has been applied to agriculture. Veterinary oversight and restrictions on inappropriate antimicrobial use have contributed to substantial reductions in antibiotic consumption among livestock. The Dutch system is supported by strong healthcare and laboratory infrastructure, which makes accurate diagnosis and monitoring easier. Its experience therefore provides an example of how prevention, diagnostics and stewardship can work together to reduce unnecessary antimicrobial use.

United States of America

The United States combines a significant AMR problem with substantial scientific, pharmaceutical and financial resources. Its response involves organisations including the CDC, FDA and USDA and covers surveillance, infection prevention, antimicrobial stewardship, agricultural use and research. The US is particularly important in antimicrobial innovation. Programmes such as CARB-X provide funding for the development of antibiotics, diagnostics and other technologies. At the same time, the economic problem surrounding antibiotics remains: successful new treatments need to be conserved, which limits their potential sales.

This has made the United States an important centre for discussions surrounding alternative R&D incentives, while its large healthcare and agricultural sectors continue to require extensive stewardship and surveillance.

Médecins Sans Frontières

Médecins Sans Frontières operates extensively in humanitarian and resource-constrained settings where healthcare facilities may lack laboratories, trained personnel, diagnostics and appropriate medicines. This can make identifying resistant infections particularly difficult, especially when treatment has to begin before laboratory results are available.

MSF has consequently focused heavily on infection prevention, antimicrobial stewardship and accessible diagnostics. Its Antibiogo project, for example, helps laboratory workers interpret antibiotic susceptibility testing in settings where specialist microbiologists may not be available.

The organisation's experience highlights the connection between AMR and healthcare access. Communities affected by resistant infections can also be those with the least access to diagnostics, appropriate medicines, WASH infrastructure and infection-prevention measures.

International Federation of Pharmaceutical Manufacturers & Associations

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) represents research-based pharmaceutical companies and is particularly relevant to the economic side of AMR. Developing a new antibiotic can require substantial investment, while the resulting product is deliberately used as little as possible in order to preserve its effectiveness. This makes antibiotics very different from most other pharmaceutical products.

This creates a difficult market situation for pharmaceutical companies. A successful new antibiotic may be scientifically valuable but commercially limited because widespread sales would itself contribute to resistance. IFPMA therefore supports economic mechanisms that provide companies with financial returns without requiring large sales volumes. These include market-entry rewards, subscription models, milestone payments and guaranteed purchasing agreements.

Push incentives can also reduce the cost and risk of development. Grants, tax incentives, public research funding and public-private partnerships can support research before a product reaches the market, while pull incentives reward successful development afterwards. Both approaches can therefore be used at different stages of the R&D process.

Access remains an important part of this discussion. A new antimicrobial needs to be available to patients who require it, including in low- and middle-income countries, while remaining protected against unnecessary use. The pharmaceutical industry's position therefore sits directly at the intersection of innovation, access, financing and stewardship, which are among the central economic challenges surrounding AMR.

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4. TOPIC 2

Establishing a Global Framework for the Regulation and Trafficking of Genome-Edited Products

4.1. Introduction to the topic

Genome editing, primarily using tools like CRISPR-Cas, Site-Directed Nucleases, and gene drives, allows precise modifications to the DNA of plants, animals, human cells, and microorganisms. While traditional Genetically Modified Organisms (GMOs) involve inserting foreign genetic material from other species, genome editing frequently involves targeted point mutations, deletions, or insertions without leaving foreign DNA. This technical distinction creates significant debate over whether genome-edited products should be subject to legacy GMO regulations or treated as conventional products.

The international landscape for genome editing is severely fragmented, raising complex biosecurity, and ethical issues:

- Process-Based vs. Product-Based Regulation: Regions like the European Union and New Zealand historically followed a process-based approach under biosafety frameworks (e.g., Cartagena Protocol), regulating products strictly based on the molecular tools used. Conversely, countries like Argentina, the United States, and Brazil utilize product-based frameworks, meaning that, if the end product contains no foreign DNA and could theoretically occur through natural mutation or conventional breeding, it is exempt from heavy GMO restrictions.
- Asymmetric Approvals and Trade Disruptions: Regulatory fragmentation creates significant cross-border challenges. A gene-edited crop approved for commercial sale in one nation may be legally classified as an unapproved GMO in another, leading to severe supply chain disruptions, rejected shipments, and legal disputes.

- Detection and Traceability Barriers: Simple targeted edits are often molecularly identical to natural genetic variations. Customs officials and regulatory enforcement agencies face technical barriers in detecting, tracking, and verifying whether imported goods have been gene-edited, complicating efforts to enforce trade standards and prevent illicit trafficking.
- Agricultural Applications vs. Human Health Governance: Beyond agriculture, genome editing presents distinct challenges in human medicine. While somatic cell therapies offer potential treatments for genetic disorders, heritable human genome editing raises significant bioethical concerns, requiring international standards to prevent unregulated medical applications and black-market therapies.

4.2. Definition of key terms

- Transgenesis vs. Cisgenesis vs. Mutagenesis:
  - **Transgenesis**: Inserting genetic material from an entirely different, non-crossable species into a host genome (the defining technical feature of traditional GMOs).
  - **Cisgenesis**: Inserting genetic material from the same or a closely related, sexually compatible species.
- Process-Based vs. Product-Based Regulation:
  - **Process-Based**: Regulates an organism based on the technology used to create it (e.g., any laboratory gene editing automatically triggers strict GMO oversight).
  - **Product-Based**: Regulates an organism based on its final characteristics (e.g., if the final crop contains no foreign DNA and could occur naturally, it bypasses GMO oversight).
- Asymmetric Approval (Asynchronous Authorization): A situation where a gene-edited product is legally approved for commercial use in an exporting country but classified as an illegal or unapproved GMO in an importing country, leading to trade blockages.

4.3 Key historical precedents: the He Jiankui Experiment

The most significant catalyst for human gene-editing governance occurred in November 2018, when Chinese researcher Dr. He Jiankui announced the birth of the world's first genome-edited human infants—twin girls known by the pseudonyms "Lulu" and "Nana".

Using CRISPR-Cas9 during in vitro fertilization (IVF), He attempted to modify the CCR5 gene in human embryos to confer genetic resistance to HIV, as the children's father was HIV-positive.

This experiment bypassed standard ethical reviews and violated global scientific consensuses. The clinical trials involved serious ethical, legal, and safety breaches:

- **Informed Consent Violations**: The parents were provided with complex consent forms labeled as an "HIV vaccine development program" rather than an experimental gene-modification procedure. The full risks of embryo editing were not adequately communicated, undermining genuine informed consent.
- **Unintended Scientific Risks**: The resulting edits did not match natural protective mutations and instead, caused off-target mutations and genetic mosaicism—a condition where different cells in the same individual carry different genetic sequences—leaving the children with unpredictable long-term health risks.
- **Lack of Medical Necessity**: Established medical protocols (such as standard sperm-washing during IVF) already prevent paternal HIV transmission safely without altering the human germline.

The international backlash was immediate. In December 2019, Chinese courts convicted He Jiankui for "illegal medical practices," sentencing him to three years in prison and imposing a 3-million-yuan fine. The event demonstrated how localized gaps in oversight can lead to global ethical violations, prompting the World Health Organization to establish its “Global Guidance Framework for Human Genome Editing” to mandate strict oversight, transparency, and accountability across all jurisdictions.

4.4. Timeline of Events

- 2000 (Adopted) / 2003 (Inforced) - Cartagena Protocol on Biosafety: Established under the UN Convention on Biological Diversity to govern the transboundary movement of "Living Modified Organisms". It serves as the primary international framework for biosafety assessments.
- 2012 - Development of CRISPR-Cas9: Scientific teams demonstrate that the CRISPR-Cas9 bacterial defense mechanism can be repurposed as a programmable, highly efficient gene-editing tool for eukaryotic cells.

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This experiment bypassed standard ethical reviews and violated global scientific consensuses. The clinical trials involved serious ethical, legal, and safety breaches:

- July 2018 - European Court of Justice Ruling (Case C-528/16): The ECJ rules that organisms obtained by targeted mutagenesis are legally GMOs under Directive 2001/18/EC, subjecting all gene-edited products in Europe to strict GMO regulations.
- November 2018 - The He Jiankui "CRISPR Babies" Experiment: Chinese scientist He Jiankui announces the birth of the world's first genome-edited human infants. The experiment triggers global condemnation and highlights critical gaps in international biosecurity enforcement.
- December 2018 / July 2019 - WHO Response: The WHO Committee establishes the Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing and launches a global registry to track clinical trials involving human gene editing.
- December 2019 - Judicial Ruling on He Jiankui: A Chinese court sentences He Jiankui to three years in prison for "illegal medical practices," establishing a domestic legal precedent against unauthorized gene editing.
- July 2021 - WHO Issues Guidance Framework: The WHO publishes Human Genome Editing: A Framework for Governance, establishing global recommendations to prevent irresponsible gene editing while supporting ethical somatic research.
- March 2023 - UK Enacts Precision Breeding Act: Post-Brexit Britain officially breaks from EU precedent, passing legislation to exempt non-transgenic "precision-bred organisms" from legacy GMO restrictions.
- June 2026 - European Union Formally Adopts New Genomic Techniques Framework: The EU approves a major reform package splitting gene-edited plants into NGT-1 (conventional-like edits exempt from GMO trials) and NGT-2 (complex edits subject to full GMO risk assessments)

4.5. Case studies

Country	Stance	Primary economic and ethical focus
People's Republic of China	Streamlined	Rapid agricultural tech development
United States of America	Product based (exemptive)	Unrestricted trade & biotech innovation
United Kingdom	Process based	Agricultural innovation & trade divergence from the EU
European Union (Germany/ Netherlands)	Transitioning	Environmental safety & market equalization
Russian Federation	Strict state control	Biological security & seed sovereignty
Republic of Brazil	Case-by-case exemption	Agricultural export competitiveness
Republic of Korea	Transitioning	Traceability, trade compliance, & labeling expansion
Republic of Cuba	State-Managed	Public health access & domestic crop resilience
Republic of Kenya	Streamlined / Exemption-Based	Climate-resilient crops & regional food security
New Zealand	Transitioning	Easing strict bans to allow regulated commercialization
Republic of Singapore	Trade-Friendly	Novel food safety, import flow, & urban food security
Medicin Sans Frontieres	Human rights - centered	Global health access

People's Republic of China

In the wake of the 2018 human embryo experiment, China overhauled its biosecurity legislation, introducing strict criminal codes for unapproved human genetic manipulation. However, in agriculture, China actively promotes genome-editing technology. In 2022, China's Ministry of Agriculture and Rural Affairs introduced streamlined guidelines for gene-edited plants. Under this system, if an edited crop contains no introduced foreign DNA, applicants can skip extensive, multi-year GMO field trials once basic safety and genetic stability are proven. This dual approach allows China to maintain absolute central oversight on human biosecurity while accelerating domestic agricultural self-reliance.

United States of America

The United States employs a strictly product-based oversight model under its Coordinated Framework for the Regulation of Biotechnology. Under the USDA's SECURE Rule, gene-edited plants carrying modifications that could theoretically be achieved through traditional plant breeding (such as single base-pair deletions or SDN-1 edits) are completely exempt from plant pest regulatory oversight. The US does not require special labeling or lengthy trials for non-transgenic edits, making it a key advocate for deregulated aligned, non-discriminatory international trade policies.

United Kingdom of Great Britain and Northern Ireland

Following its exit from the European Union, the United Kingdom deliberately parted ways with the strict European precedent set by Directive 2001/18/EC. In 2023, the UK enacted the Genetic Technology (Precision Breeding) Act, creating a dedicated legal category for "precision-bred organisms. (PBOs) - defined as plants and animals carrying genetic changes that could have occurred naturally or through traditional breeding methods. By legally separating PBOs from traditional, transgenic GMOs, the UK streamlined the commercialization process, eliminating lengthy field-trial requirements and reducing market approval timelines. The UK's primary economic focus is positioning itself as a global hub for agri-tech innovation and climate-resilient crop development. However, this regulatory divergence creates significant cross-border trade friction, particularly with its neighboring EU trading partners, who continue to enforce strict GMO tracking and labeling standards on imported agricultural products.

European Union (Netherlands & Germany)

As influential member states of the European Union, Germany and the Netherlands operate under the historic 2018 European Court of Justice ruling, which concluded that all organisms modified via genome editing fall under the strict precautionary directives of EU Directive 2001/18/EC. This subjects gene-edited crops to comprehensive risk assessments, environmental impact monitoring, and mandatory GMO labeling.

However, both nations sit at the center of ongoing EU legislative efforts to introduce a dedicated framework for New Genomic Techniques (NGTs). While Germany balances consumer protection with scientific competitiveness, the Netherlands—a major exporter of plant seeds—strongly advocates for exempting non-transgenic NGTs to prevent European agricultural technologies from falling behind global markets.

Russian Federation

Russia enforces a precautionary framework that prioritizes state security, food sovereignty, and centralized oversight. Under its federal laws on genetic engineering, commercial cultivation of modified crops remains heavily restricted. All imported or domestic biotech products must undergo rigorous state registration, laboratory validation, and safety evaluations. Russia views automated international regulatory harmonisation with skepticism, preferring to maintain strict national control over its domestic seed supply and agricultural trade borders to guard against foreign biotech monopolies.

Republic of Brazil

Brazil was an early leader in establishing clear, predictable rules for agricultural gene editing. Through CTNBio (its national biosafety commission), Brazil utilizes Normative Resolution No. 16 to evaluate gene-edited products on a case-by-case basis. If CTNBio determines that a modified product lacks persistent foreign DNA and contains genetic changes achievable through natural mutation or conventional cross-breeding, the product is formally classified as a non-GMO. This streamlined, product-based approach has enabled Brazil to integrate gene-edited crops into its massive agricultural export infrastructure without incurring heavy compliance costs.

Republic of Korea

South Korea traditionally governed gene-edited products under a strict, process-based regime via its Transboundary Movement of Genetically Modified Organisms Act. While the government has discussed streamlining approvals for non-transgenic edits, South Korea maintains rigorous tracking, labeling, and trade oversight. In 2026, the Ministry of Food and Drug Safety (MFDS) significantly broadened biotech labeling rules to require mandatory GMO labeling for processed items (such as soy sauce, sugars, and oils) even when modified DNA is no longer detectable.

South Korea's stance reflects a delicate balance: supporting domestic scientific research while enforcing absolute supply-chain transparency, mandatory consumer disclosures, and cautious border oversight.

Republic of Cuba

Cuba approaches biotechnology through a state-administered, centralized model overseen by the National Centre for Biological Safety (CSB). Unlike Western systems that focus on corporate deregulation or market-driven intellectual property rights, Cuba prioritizes public health therapeutics and national food security. Cuban researchers actively apply genetic techniques to develop dengue treatments, cancer immunotherapies, and climate-resilient crops. Cuba's regulatory model emphasizes strict biosecurity, state oversight, and national sovereignty, rejecting pure deregulation while advocating for equitable global access to biological technologies without corporate monopolies.

Republic of Kenya

Kenya stands as a regional leader for agricultural biotechnology in Africa. Through its National Biosafety Authority (NBA), Kenya introduced clear national guidelines that explicitly exempt genome-edited products from heavy GMO regulations—provided the final organism contains no introduced foreign DNA (such as SDN-1 and SDN-2 edits). Facing severe droughts, changing weather patterns, and crop diseases, Kenya relies on gene-editing technology to develop resilient staple crops like disease-resistant cassava and drought-tolerant maize. Kenya represents developing nations using risk-proportionate regulatory frameworks to accelerate agricultural resilience and secure domestic food supplies.

New Zealand

New Zealand historically applied one of the world's strictest precautionary stances under the Hazardous Substances and New Organisms (HSNO) Act 1996, which legally classified all gene-edited organisms as traditional GMOs regardless of whether foreign DNA remained. However, to prevent falling behind international scientific standards, New Zealand initiated sweeping legislative reforms to replace its decades-old framework.

The new risk-tiered approach establishes a dedicated regulator to exempt low-risk, non-transgenic gene-editing techniques while maintaining strict safety controls, making New Zealand a primary case study of a nation transitioning from a strict precautionary regime to a modern, commercial-friendly system.

Republic of Singapore

As a densely populated urban state that imports over 90% of its food, Singapore prioritizes trade efficiency, novel food innovation, and supply chain resilience. Governed through the Genetic Modification Advisory Committee (GMAC), Singapore utilizes a flexible, risk-tiered approval process. Gene-edited crops, ingredients, and cultivated meats containing no foreign genetic material undergo streamlined safety evaluations rather than full-scale GMO trials. Singapore acts as an international baseline for how small, import-reliant economies can regulate gene-edited products to ensure food safety without creating technical barriers to global trade.

Medecin Sans Frontieres

From an international humanitarian perspective, MSF focuses on the severe global health inequities surrounding medical genome editing. Advanced gene therapies—such as CRISPR-based treatments for sickle cell disease—carry price tags exceeding millions of dollars per patient, rendering them virtually inaccessible in low- and middle-income countries where disease burdens are highest. MSF advocates for international governance frameworks that enforce equitable access mechanisms, fair pricing models, technology transfers, and strict safeguards to prevent vulnerable populations from being exploited in unapproved or unsafe clinical trials.

4.6. Relevant Treaties

Cartagena Protocol on Biosafety

-> Governs the cross-border movement, transit, and handling of Living Modified Organisms (LMOs)

-> Parties continuously debate whether non-transgenic gene-edited organisms fall under the legal definition of an LMO ("any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology")

World Trade Organisation Agreements

-> SPS Agreement (Sanitary and Phytosanitary Measures): Mandates that national health and safety restrictions on imports must be based on scientific risk assessments.

-> TBT Agreement (Technical Barriers to Trade): Prevents technical regulations and labeling requirements from creating unnecessary obstacles to international trade. Unreasonable bans on gene-edited imports can be challenged under these rules.

Codex Alimentarius Commission

-> Sets international food safety codes, guidelines, and standards

-> Provides scientific definitions and safety assessment protocols for foods derived from modern biotechnology, helping standardize international customs evaluations.

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