AMR INDUSTRY ALLIANCE

Equitable & Responsible Access Roadmap

FEBRUARY 2024





Introduction

Many countries and patient populations lack access to appropriate antimicrobial treatments, resulting in undue health burdens and increased mortality. According to the World Health Organization, access to quality-assured, essential antimicrobials is critical to reducing the spread of antimicrobial resistance (AMR). As one of the largest private sector coalitions set up to provide sustainable solutions to curb AMR, the AMR Industry Alliance (the Alliance) is committed to improving equitable access to antimicrobials and diagnostic technologies. Ensuring sustainable, equitable, and appropriate access to antimicrobial products requires collaborative, multisectoral, and patient-oriented solutions to access challenges.

This roadmap addresses barriers that are limiting access for patients around the world, and for which there is opportunity for progress through multistakeholder action: barriers related to diagnostics infrastructure, diagnostics valuations and funding, antimicrobial regulatory issues, demand forecasting, and antimicrobial procurement challenges. The roadmap offers a collaborative framework for members of the private and public sectors to tackle these access barriers and strengthen healthcare systems.

In the lead-up to the United Nations General Assembly Highlevel Meeting (HLM) on AMR, the Alliance calls for greater partnership between governments, civil society organizations, and the private sector to improve patient access to appropriate diagnostics and antimicrobials worldwide.

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Background

Antimicrobials and infectious disease diagnostics have together revolutionized medicine over the past century. They have helped cure and treat many infectious diseases that previously posed severe threats to human health. Furthermore, by protecting against infections, antimicrobials make practices such as surgery and cancer care possible. Since their introduction approximately 100 years ago, antimicrobials have been estimated to add an average of 23 years to global lifespans. Diagnostics, in turn, play a vital role in disease treatment and in preserving the effectiveness of antimicrobials by helping medical professionals understand what treatments are appropriate for their patients. Together, these innovations are the foundation of effective health systems — that is why it is so important that patients have access to appropriate antimicrobials and diagnostics when they need them.

Multiple estimates suggest that global antimicrobial consumption is on the rise,^{3,4} with some studies showing that antibiotic usage increased by as much as 46% from 2000 to 2018.³ Paradoxically, many patients around the world can access only a limited range of antimicrobials and may not have access to diagnostics at all. Misuse of antimicrobials, whether through overuse when an antimicrobial is not medically indicated or through the use of an inappropriate antimicrobial when the right treatment isn't available, is a major driver of AMR. Antimicrobial stewardship practices that can delay the rise of AMR require access to effective antimicrobials and diagnostics.



To help promote stewardship and enable appropriate access worldwide, the World Health Organization (WHO) developed the AWaRe (Access, Watch, and Reserve) classification system for antibiotics. First published in 2017, the AWaRe list is updated every two years by the WHO Expert Committee on Selection and Use of Essential Medicines. The AWaRe classification organizes antibiotics into "Access," "Watch," and "Reserve" groups while also suggesting combinations of antibiotics that should not be used together in clinical practice.

The Access group

includes antibiotics with a narrow spectrum of activity that are used for empiric treatment and should be widely available.

The Watch group

contains antibiotics that are more commonly used in sicker patients in hospital settings that should be carefully monitored to avoid overuse.

The Reserve group

contains antibiotics considered as backup options for use only when specifically needed to treat multi-drug resistant infections ⁵

The AWaRe classification currently covers 258 drugs.^a To encourage appropriate use, WHO set a target calling for 60% of global antibiotic consumption to be Access group antibiotics in 2023.⁶ A 2021 examination of sales data from 76 countries between 2000 to 2015 found that 45% (42 out of 76 countries) were not achieving this goal.⁷ This result suggests that there is a worldwide problem with the appropriate use of antimicrobials and that patients often do not have access to appropriate antimicrobials when they need them.

^a This definition comes from World Health Organization documentation on AMR³²

Access to diagnostics is also challenging in many parts of the world. Although diagnostics have been found to impact between 60% and 70% of all healthcare decisions, research suggests that nearly half the world's population have little or no access to any diagnostics tests. Successful use of diagnostics for infectious disease cases can help patients get the right treatments sooner, facilitating their recovery and slowing the rise of AMR. Conversely, without access to testing, doctors must treat patients based on incomplete information. In such cases, patients may be subjected to ineffective treatments or treatments that contribute to resistance. Diagnostics play a vital role in enabling the targeted and appropriate use of antimicrobials, which have the potential to improve patient outcomes and reduce the spread of AMR.

The AMR Industry Alliance has set out commitments related to improving patient access to antimicrobials and diagnostics. In support of those commitments, the Alliance has supported research and analysis on key access barriers, including health system weaknesses, 10 supply chain vulnerabilities, issues with unpredictable demand, market access challenges, 11 and regulatory frameworks. 12 Additionally, individual companies within the Alliance have undertaken independent activities to support global access. 13 However, further action is needed by all stakeholders. This roadmap suggests areas where members of the public and private sectors could work together to ensure antimicrobials and diagnostic technologies are available to the patients and medical professionals who need them.

ALLIANCE COMMITMENTS ON ACCESS

Address barriers to patient access to the most appropriate treatment, vaccine or diagnostic.

Work in collaboration with policymakers to create an economic and regulatory environment that enables the sustainable supply of quality-assured antibiotics

Work to reduce the prevalence of substandard and falsified AMR-relevent products.

Improving Diagnostics Access and Infrastructure

Diagnostic technology is crucial for appropriately treating patients and preventing the development and spread of AMR. When a sick patient presents to a medical facility, it is often not immediately apparent what illness the patient suffers from. In these cases, regardless of location, if an infectious disease is suspected, but no data are available to help diagnose the cause, doctors will often prescribe broad-spectrum antibiotics as a precautionary measure. If the patient gets better, the problem is solved. If the patient does not, the doctor may reassess the treatment plan and try other antibiotic options. This "empiric" treatment of infectious disease patients is the current reality for patient care worldwide; the practice contributes to antimicrobial overuse and misuse, which which accelerates the development of resistance.²

Diagnostics can help healthcare providers avoid the downsides of empiric prescribing. It is estimated that between 30% and 50% of antibiotics prescribed to humans may be inappropriate. 14 Diagnostics can determine if the cause of an illness is due to an infection, the type of infection, and what antimicrobials would be most appropriate to treat the infection. Depending on the test used, diagnostics can also help doctors arrive at the right treatment decision much quicker than would be possible through empiric trial and error. Additionally, once an individual has initiated antibiotic treatment, diagnostics can enable treatment monitoring to guide whether antibiotics can be discontinued for more optimized utilization.



Too many people around the world still have little to no access to diagnostics. Numerous factors contribute to this situation. Complexity among diverse regulatory systems can make it challenging for manufacturers to quickly make new diagnostics available worldwide. Even in countries where diagnostics are approved, broader adoption requires adequate clinic and laboratory infrastructure, including a sufficient number of trained technicians in the workforce, to collect samples, perform quality testing, and deliver reliable results at the speed and volume required by health systems for patient care. Testing is also heavily reliant on communications technology, which is essential to facilitate test ordering and reporting of results to medical providers in a reasonable time.

Furthermore, for adoption to be achieved, diagnostics must be reimbursed at a level that makes them a good investment for clinics, laboratories, hospitals, and health systems, and prices must be set to allow for the sustainable manufacturing of testing instruments and kits. For diagnostics to be utilized appropriately for the benefit of patients, there must be education and awareness about the clinical utility of testing and its crucial role in guiding optimal antimicrobial prescribing. Any of the aforementioned challenges can prevent access to testing, limit optimal test utilization, or delay results, which can drive inappropriate antibiotic use, potentially leading to worse patient outcomes and increasing AMR.

Many of the diagnostics-related issues described above also impact access to antimicrobials. A lack of accurate data on resistance patterns and limited access to diagnostics can affect antimicrobial development decisions and launch plans. Without accurate and up-to-date surveillance information provided by diagnostics technology, there is no way to tell where new antimicrobials are needed.

Among the many challenges of diagnostics access, this roadmap section considers infrastructure as well as value recognition and investment issues.



Barriers to Diagnostics Access

Diagnostic Access Barriers and Solutions at a Glance

Dollar State		£	
Priority	area	tor	access

Issue

Call to Action

Actors

Diagnostics Infrastructure

Inadequate health system infrastructure hinders the introduction and appropriate use of diagnostics technology Ensure microbiology labs get proper resources to implement the diagnostic solutions necessary to speed up the time to result and the time to effective therapy, in particular by promoting more rapid and informative tests, more effective datahandling tools, and maximizing the efficiency of centralized or decentralized testing.

Governments, multilateral organizations, NGOs

Recognition of the Value of Diagnostic Technology

In many health systems, diagnostics technology is available but not optimally utilized Create and support training programs around the importance of diagnostics to clinical care and surveillance, including the use of technology to promote the appropriate use of antimicrobials and antimicrobial stewardship. Ensure that healthcare systems have incentives to use diagnostics through appropriate reimbursement mechanisms.

Governments, healthcare professionals, civil society, private sector

In places where the value of testing isn't recognized, it is difficult for the private sector to invest further into the introduction of new technology

Demonstrate the value of diagnostics to society using robust and indisputable methodology within pricing and health technology assessments.

Governments, academics, private sector

01 Diagnostics Infrastructure

The issue

Diagnostics are only useful if tests can be ordered at an appropriate time and performed with quality assurance, with results communicated back to medical professionals in a timely manner. Research shows that in countries across all income bands, but particularly in low- and middle-income countries (LMICs), laboratory infrastructure is inadequate. Problems with electricity, biosafety requirements, internet connectivity, supply chain stability (including for essential chemicals and substances needed for conducting tests), laboratory workforce capacity, and other issues can result in a lack of access to testing or quality issues and delays that may, in some cases, render test results meaningless for patient treatment. Even if available, diagnostics cannot benefit patients without the infrastructure in place to support its use.

What can be done to

As part of commitments towards achieving Universal Health Coverage, governments around the world have committed to achieving access to quality, safe, effective, affordable, and essential diagnostics for all people by 2030. 18 This will only be possible if governments commit to laying the groundwork that make diagnostic testing possible. Sustainable clinic and laboratory infrastructure improvements must be prioritized by governments as part of strategies to improve health system sustainability and resilience.

There is no one-size-fits-all solution; actions should be tailored to the specific barriers relevant to the local contact and can include improvements to electricity, internet connectivity, biosafety requirements, laboratory workforce capacity, and resource availability. Better resourced labs can invest in faster, more informative tests and better data infrastructure that enable them to work more effectively and optimize reporting of results.

02

Recognition of the Value of Diagnostic Technology

The issue

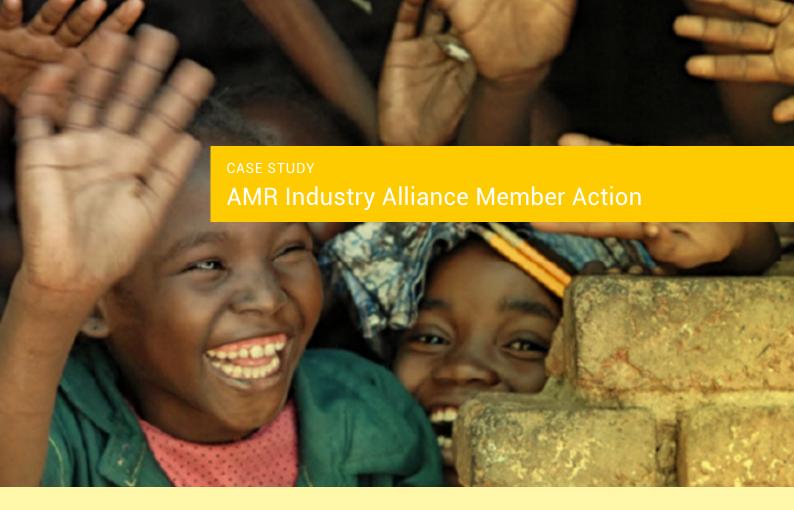
Even in health systems around the world where diagnostics are available and accessible, they must be used by healthcare providers to have an impact. Diagnostics offer many benefits: they improve patient health by facilitating earlier diagnosis and optimal prescribing; they save money for healthcare systems by improving patient outcomes¹⁹; and they prevent the spread of antimicrobial resistance by helping doctors prescribe the right antimicrobial. Diagnostics can positively transform healthcare decision-making. Yet, despite their clear benefits, health professionals do not always use diagnostics to inform clinical practice.

Low awareness about the value of testing can lead to insufficient budgets for diagnostic technology. Where the relative value of testing is not recognized, there is no demand for further investments into testing, and as such, testing infrastructure cannot be developed in such a way that would make the tests more accessible and useful to medical professionals. Research suggests that even in high-income countries, diagnostics are underfunded.^{8,19}

What can be done to

Efforts to improve the utilization of existing diagnostic technology could quickly enhance access for many people around the world. Governments and academic institutions could do much to improve health care quality by creating and expanding training programs for healthcare professionals about the value of the tests currently available to them for clinical care and surveillance and the usefulness of testing for antimicrobial stewardship.

Efforts should be made to prove that value through robust and indisputable methodology, and Governments should recognize that evidence in pricing and health technology assessments. There have been calls for countries worldwide to consider the benefits of more robust testing infrastructure and work toward the goal of allocating 4% of health budgets for diagnostics.²⁰ This enhancement would help bring diagnostics to more people over time.



Members of the AMR Industry Alliance are already working to address the issues described above in countries around the world. For example, over the past few decades, health infrastructure and equipment have deteriorated in Cote d'Ivoire due to poor economic conditions and a lack of healthcare funding. In 2018, the Ministry of Health (MOH) began working to address this issue, creating a new initiative that aims to construct twenty 120-200 bed hospitals in the country, positioning Cote d'Ivoire as a hub for healthcare in the West African sub-region. This initiative recognized the importance of diagnostics infrastructure in the form of funding to create laboratories. In 2020, bioMérieux was awarded contracts to integrate its blood culture and infectious disease (ID) & antimicrobial susceptibility testing (AST) solutions into 18 of the new hospitals.

In Cote d'Ivoire, as in many countries, just having diagnostic technology is not enough to ensure the effective and appropriate use of testing. To address this, bioMérieux did not just install technology; it also implemented training and awareness programs. The company helped hospitals integrate new technology into the latest AMR management guidelines, funded education programs for healthcare professionals, created a segment on AMR awareness in a local television show, and ran a program on sanitation for the public. With the funding from the Government alongside the awareness and training efforts of bioMérieux, patients at the new hospitals in Cote d'Ivoire now have enhanced access to diagnostic technology.

Improving Antimicrobial Access

Lack of access to life-saving antimicrobials remains a global problem. Surveys by the WHO and other groups suggest multiple challenges related to the sustainable availability of antibiotics (both novel and generic) around the world.^{21,22} A 2018 study found that only 12 of the 25 novel antibiotics approved between 1999 and 2014 were registered in more than 10 countries.²³ A 2022 study that examined 14 high-income countries, where it might be expected that the resources and infrastructure exist to support better access, found that even in these countries, there is limited or delayed access to many of the new antibiotics first approved between 2010 and 2020.²⁴ The Access to Medicines Foundation 2021 AMR Benchmark reported that just 14% of generic antibiotics are registered in more than ten of the 102 low- and middle-income countries researched.²⁵

These access gaps are the result of complex and unharmonized regulatory systems, antibiotic prices too low to cover costs, logistical issues, and a lack of demand predictability, among other issues. Equitable and sustainable access to antimicrobials will require coordinated action from a wide range of stakeholders in every country.



It is estimated that 5.7 million people die each year in LMICs due to a lack of access to antibiotics.²⁶ As already noted, even in situations where there is access to antimicrobials, patients do not necessarily always have access to the most appropriate antimicrobial for their case. It is crucial that stakeholders around the world work to ensure that every patient has access to the right antibiotic at the right time.

Toward improving antimicrobial access, this roadmap focuses on the barriers of regulatory issues, demand forecasting, and procurement challenges. While these are not the only challenges impacting access, taking action in these areas could significantly increase the availability of necessary antibiotics across the world.



Barriers to Antimicrobial Access

Antimicrobial Access Barriers and Solutions at a Glance

Priority area for access

Issue

Call to Action

Actors

Antibiotic Regulatory Issues

Registration processes in many countries are inefficient.
Limited resources for registration and differing requirements across countries limit where companies seek approval for antibiotics

Enhance regulatory efficiencies and reduce cost barriers to market entry by allowing for flexibility in registration dossier requirements and by making use of reference approvals, reliance mechanisms, and WHO pregualification when possible. Governments, multilateral organizations

Forecasting and Surveillance

Without accurate data on infectious disease trends and resistance rates, decisions about new registrations and manufacturing volume are difficult, creating barriers to the access of antimicrobials.

Increase investment into diagnostics and health data infrastructure needed for the surveillance of diseases, antimicrobial use, and resistance. Encourage microbiology labs to collaborate on infection control and the surveillance of resistant organisms. Leverage surveillance data for demand forecasts communicated to manufacturers.

Governments, private sector, multinational organizations

Antibiotic procurement challenges

Procurement policies can drive the prices of antibiotics down to the point where the price of any drug is too low to allow for its continued manufacturing and supply to the market

Develop pricing and reimbursement methodology that better reflects the value that antibiotics bring to society.

Governments, academia

Consider the development of subscription or other new payment models for antibiotics to incentivize access rather than the volume of drug sold.

Governments, academia, multinational organizations

03 Antibiotic Regulatory Issues

The issue

Before an antibiotic can be used, it must be registered in the country where the use will happen. However, differing requirements for registration mean that it can take years for companies to submit and secure regulatory approval in multiple countries. It is impossible to develop and use a single registration dossier to obtain approval worldwide. This is not just an issue for antibiotics; it is a problem for all medicines. However, it is a particularly challenging barrier for antibiotics, which already face viability challenges. The varying complexity and requirements of different registration systems compound this problem. For instance, many countries require locally conducted clinical trials or trial results from specific populations. Complex and unharmonized regulatory processes, combined with resource restrictions, create a significant barrier to antibiotic access for both novel and generic medicines.

What can be done to address this issue?

Changes to regulatory processes could help to enhance access for patients. A 2022 study supported by the AMR Industry Alliance on regulatory issues related to antibiotics in three LMICs done by One Health Trust found common solutions to diverse regulatory issues across countries: regulatory system strengthening and regulatory harmonization. Pegulatory systems could be improved by waiving requirements for in-country trial data, reducing financial disincentives to market entry, and making use of reference approvals where possible. Countries should also consider reliance mechanisms, including working with the WHO on the collaborative procedure for accelerated registration of prequalified finished pharmaceutical products. Procedure for accelerated registration

04 Forecasting and Surveillance

The issue

Forecasting in healthcare is a challenge.²⁸ For antimicrobials, the inability to accurately forecast infectious disease patterns and resistance can lead to supply constraints. A lack of data on the potential demand for antimicrobials can make it difficult for the industry to assess unmet medical needs and make decisions about where to seek registration and launch antimicrobials. Forecasting demand is particularly important because adjustments to production and supply chain can be lengthy and costly, especially if a new facility is required. Facilities are run at maximum utilization to optimize costs, reducing flexibility to ramp up production in the case of demand surges or to cover a shortfall by another manufacturer.

Demand can be hard to forecast for many reasons. Among them, resistance patterns and localized infectious disease outbreaks are difficult to predict, the development, revision and adoption of treatment guidelines can impact demand for specific products, and, in many countries, there are limitations to the amount of data available. Diagnostic infrastructure is crucial to this issue; robust surveillance systems supported by diagnostic technology are necessary to understand infectious disease trends and resistance rates. Even when forecasts based on epidemiologic studies and surveillance data exist, the forecast may not be supported by adequate health system financing, and the translation of forecast data into procurement may differ substantially from the demand suggested by studies.

What can be done to address this issue?

Improving health data infrastructure and expanding the use of diagnostic technology to inform resistance and antibiotic consumption surveillance systems could help to improve forecasting in many countries. A 2022 report supported by the AMR Industry Alliance found that surveillance practices continue to be underdeveloped in many countries. This is yet another reason why diagnostics and laboratory infrastructure improvements are so important. Policies are needed to encourage more microbiology labs to collaborate on surveillance and infection control. Particularly in LMICs, there are opportunities for governments and the private sector to work together toward strengthening infrastructure to better track changes in antimicrobial use. This infrastructure is also important for monitoring falsified antibiotics, which are estimated to comprise 5% of the global pharmaceutical market. Better monitoring could help connect the high-quality antimicrobials to the right patients at the right time.

05 Antibiotic Procurement Challenges

The issue

Antibiotic procurement policies and practices can create challenges for access across countries of any income level. A 2022 report supported by AMR Industry Alliance noted many instances where health systems faced challenges in obtaining sufficient supply due to unsustainable procurement practices, including the cases of price caps on benzathine penicillin G, price controls in India on cefazolin, and single supplier contracts in Germany that have all been associated with shortages. 11 These policies and practices, particularly for generic antibiotics, can drive the prices of all products down to the point where the price of an antibiotic is too low to allow for its continued manufacturing and supply to the market. They can also lead to supplier consolidation (for both finished products and active pharmaceutical ingredients (API)), which reduces supply chain resilience and can introduce the risk of shortages and stockouts. 11 For novel antibiotics, procurement policy challenges include health technology assessments and reimbursement systems that do not capture the full value these products bring. Taken together, pricing pressures introduced by procurement policies can severely hinder efforts to sustainably supply antibiotics across the world.

What can be done to

A 2022 report supported by AMR Industry Alliance examined this issue and made several recommendations, including pricing and reimbursement processes that reflect the actual value of antibiotics to society, and the development of new payment models to encourage antibiotic availability in participating countries.¹¹

The report's recommendations include revising pricing policies for off-patent antibiotics, ensuring a balance between cost-effectiveness for health systems and viability for suppliers. This involves reevaluating prices for medicines at risk of shortages. Another key strategy is the implementation of de-linked subscription models, which would shift the focus from sales volume to the value of ensuring the availability of antibiotics, enabling financial predictability for manufacturers and aligning incentives with public health objectives. Additionally, sustainable tender policies that involve multiple suppliers in the procurement process are suggested to foster a competitive and stable market, reducing the risk of shortages and ensuring a more reliable supply of antibiotics. This approach aims to address the challenges of supply chain sustainability in both high-income and low- and middle-income countries, contributing to improved global access to essential antibiotics.



Many AMR Industry Alliance members have initiatives aimed at improving access to antimicrobials. For instance, Fresenius Kabi has an initiative to introduce older, generic antimicrobials to low and middle-income countries. Alliance members Otsuka, Johnson and Johnson, and Viatris are working to overcome registration challenges related to treatments for multidrug-resistant tuberculosis. Johnson and Johnson has applied for the registration of bedaquiline in 72 countries across the world. Otsuka and Viatris have worked to make delamanid available across 127 countries, with Otsuka establishing compassionate use programs in countries where approval is unavailable due to regulatory approval delays or other issues. Viatris has also partnered with MedAccess and TB Alliance to reduce the price of pretomanid and expand access, in addition to creating a named patient access program in countries where the drug is not registered and undertaking product donations.

Alliance member **Shionogi** is working with the Global Antibiotic Research and Development Partnership (GARDP) and the Clinton Health Access Initiative (CHAI) on a collaboration aimed at accelerating access to cefiderocol in 135 countries.³¹ The collaboration has an objective of prioritizing access in places where public health need and AMR burden are highest. The collaboration agreement includes provisions to work with government, public, and private sector experts to strengthen hospital-based stewardship programs and appropriate use. Ensuring patient access will require overcoming different challenges, including technical, regulatory, and economic barriers.

Through these examples and other initiatives, Alliance members are working to do their part to overcome regulatory, forecasting, and procurement issues to enhance antimicrobial access.

Conclusion

Addressing the complex access barriers for antimicrobials and diagnostics will require collaboration from a broad range of stakeholders. The AMR Industry Alliance has developed this roadmap as a starting point for impactful engagement with other stakeholders committed to the fight against AMR. This roadmap suggests key areas where action could be taken to significantly improve access worldwide. It is hoped that other stakeholders will partner with the AMR Industry Alliance in working toward solutions to these issues.



Barriers to Access

Access Barriers and Solutions at a Glance

Priority area for access	Issue	Call to Action	Actors
Diagnostics Infrastructure	Inadequate health system infrastructure hinders the introduction and appropriate use of diagnostics technology	Ensure microbiology labs get proper resources to implement the diagnostic solutions necessary to speed up the time to result and the time to effective therapy, in particular by promoting more rapid and informative tests, more effective datahandling tools, and maximizing the efficiency of centralized or decentralized testing.	Governments, multilateral organizations, NGOs
Recognition of the Value of Diagnostic	In many health systems, diagnostics technology	Create and support training programs around the importance	Governments, healthcare

Technology

is available but not optimally utilized

of diagnostics to clinical care and surveillance, including the use of technology to promote the appropriate use of antimicrobials and antimicrobial stewardship. Ensure that healthcare systems have incentives to use diagnostics through appropriate reimbursement mechanisms.

professionals, civil society, private sector

In places where the value of testing isn't recognized, it is difficult for the private sector to invest further into the introduction of new technology

Demonstrate the value of diagnostics to society using robust and indisputable methodology within pricing and health technology assessments. Governments, academics. private sector



Barriers to Access (continued)

Access Barriers and Solutions at a Glance

Priority area for access

Issue

Call to Action

Actors

Antibiotic Regulatory Issues

Registration processes in many countries are inefficient.
Limited resources for registration and differing requirements across countries limit where companies seek approval for antibiotics

Enhance regulatory efficiencies and reduce cost barriers to market entry by allowing for flexibility in registration dossier requirements and by making use of reference approvals, reliance mechanisms, and WHO pregualification when possible. Governments, multilateral organizations

Forecasting and Surveillance

Without accurate data on infectious disease trends and resistance rates, decisions about new registrations and manufacturing volume are difficult, creating barriers to the access of antimicrobials.

Increase investment into diagnostics and health data infrastructure needed for the surveillance of diseases, antimicrobial use, and resistance. Encourage microbiology labs to collaborate on infection control and the surveillance of resistant organisms. Leverage surveillance data for demand forecasts communicated to manufacturers.

Governments, private sector, multinational organizations

Antibiotic procurement challenges

Procurement policies can drive the prices of antibiotics down to the point where the price of any drug is too low to allow for its continued manufacturing and supply to the market

Develop pricing and reimbursement methodology that better reflects the value that antibiotics bring to society.

Governments, academia

Consider the development of subscription or other new payment models for antibiotics to incentivize access rather than the volume of drug sold.

Governments, academia, multinational organizations

References

- 1. Hutchings M, Truman A, Wilkinson B. Antibiotics: past, present and future. Curr Opin Microbiol. 2019;51:72-80. doi:10.1016/j. mib.2019.10.008
- 2. World Health Organization. Antimicrobial resistance Fact Sheet. Published 2023. Accessed January 30, 2024. https:// www.who.int/newsroom/fact-sheets/detail/ antimicrobial-resistance
- 3. Browne AJ, Chipeta MG, Haines-Woodhouse G, et al. Global antibiotic consumption and usage in humans, 2000–18: a spatial modelling study. Lancet Planet Health. 2021;5(12):e893-e904. doi:10.1016/S2542-5196(21)00280-1
- 4. Klein EY, Van Boeckel TP, Martinez EM, et al. Global increase and geographic convergence in antibiotic consumption between 2000 and 2015. Proc Natl Acad Sci U S A. 2018;115(15):E3463-E3470. doi:10.1073/pnas.1717295115
- 5. Zanichelli V, Sharland M, Cappello B, et al. The WHO AWaRe (Access, Watch, Reserve) antibiotic book and prevention of antimicrobial resistance. Bull World Health Organ. 2023;101(4):290-296. doi:10.2471/BLT.22.288614
- 6. World Health Organization. 2021 AWaRe classification. Published online 2021. Accessed June 3, 2023.

- https://www.who.int/ publications/i/item/2021aware-classification
- 7. Klein EY, Milkowska-Shibata M, Tseng KK, et al. Assessment of WHO Antibiotic Consumption and Access Targets, 2000-2015: An Analysis of Pharmaceutical Sales Data from 76 Countries.; 2021. Accessed June 4, 2023. https://pubmed.ncbi.nlm.nih.gov/32717205/
- 8. Rohr UP, Binder C, Dieterle T, et al. The value of in vitro diagnostic testing in medical practice: A status report. PLoS One. 2016;11(3). doi:10.1371/ journal.pone.0149856
- 9. Fleming KA, Horton S, Wilson ML, et al. The Lancet Commission on diagnostics: transforming access to diagnostics. The Lancet. 2021;398(10315):1997-2050. doi:10.1016/S0140-6736(21)00673-5
- 10. Frost I, Craig J, Joshi J, Faure K, Laxminarayan R. Access Barriers to Antibiotics.; 2019.
- 11. Wilsdon T, Armstrong H, Sunil S, Associates CR. Strengthening the Sustainability of the Off-Patent Antibiotic Supply Chain FINAL REPORT.; 2023.
- 12. Kalanxhi E, Parameswaran GG, Wijk M Van, et al. DRUG REGULATORY APPROVALS AND OPPORTUNITIES FOR ANTIMICROBIAL.; 2022.

- 13. AMR Industry Alliance. In Action Access.
- 14. van Belkum A, Bachmann TT, Lüdke G, et al. Developmental roadmap for antimicrobial susceptibility testing systems. Nat Rev Microbiol. 2019;17(1):51-62. doi:10.1038/ s41579-018-0098-9
- 15. Iskandar K, Molinier L, Hallit S, et al. Surveillance of antimicrobial resistance in low- and middle-income countries: a scattered picture. Antimicrob Resist Infect Control. 2021;10(1). doi:10.1186/s13756-021-00931-w
- 16. Otaigbe II, Elikwu CJ. Drivers of inappropriate antibiotic use in low- and middle-income countries. JAC Antimicrob Resist. 2023;5(3). doi:10.1093/jacamr/dlad062
- 17. Powell L, Sittig DF, Chrouser K, Singh H. Assessment of Health Information Technology-Related Outpatient Diagnostic Delays in the US Veterans Affairs Health Care System: A Qualitative Study of Aggregated Root Cause Analysis Data. JAMA Netw Open. 2020;3(6). doi:10.1001/ jamanetworkopen.2020.6752
- 18. United Nations. Political Declaration of the High-level Meeting on Universal Health Coverage "Universal health coverage: moving together to build a healthier world." Published online 2019.

- 19. Moore LSP, Villegas MV, Wenzler E, et al. Rapid Diagnostic Test Value and Implementation in Antimicrobial Stewardship Across Low-to-Middle and High-Income Countries: A Mixed-Methods Review. Infect Dis Ther. Published online June 1, 2023. doi:10.1007/s40121-023-00815-z
- 20. Horton S, Sullivan R, Flanigan J, et al. Delivering modern, high-quality, affordable pathology and laboratory medicine to low-income and middle-income countries: a call to action. The Lancet. 2018;391(10133):1953-1964. doi:10.1016/S0140-6736(18)30460-4
- 21. Shafiq N, Pandey AK, Malhotra S, et al. Shortage of essential antimicrobials: A major challenge to global health security. BMJ Glob Health. 2021;6(11). doi:10.1136/ bmjqh-2021-006961
- 22. Cox JA, Vlieghe E, Mendelson M, et al. Antibiotic stewardship in low- and middle-income countries: the same but different? Clinical Microbiology and Infection. 2017;23(11):812-818. doi:10.1016/j.cmi.2017.07.010
- 23. Kallberg C, Ardal C, Blix HS, et al. Introduction and geographic availability of new antibiotics approved between 1999 and 2014. PLoS One. 2018;13(10). doi:10.1371/journal. pone.0205166

- 24. Outterson K, Orubu ESF, Rex J, Ardal C, Zaman MH. Patient Access in 14 High-Income Countries to New Antibacterials Approved by the US Food and Drug Administration, European Medicines Agency, Japanese Pharmaceuticals and Medical Devices Agency, or Health Canada, 2010-2020. Clinical Infectious Diseases. 2022;74(7):1183-1190. doi:10.1093/cid/ciab612
- 25. Access to Medicine Foundation. Antimicrobial Resistance Benchmark 2021. Published online 2021.
- 26. Daulaire N, Bang A, Tomson G, Kalyango JN, Cars O. Universal Access to Effective Antibiotics is Essential for Tackling Antibiotic Resistance. Journal of Law, Medicine and Ethics. 2015;43(S3):17-21. doi:10.1111/jlme.12269
- 27. World Health
 Organization. Collaborative
 Procedure for Accelerated
 Registration WHOPrequalication of Medical
 Products (IVDs, Medicines,
 Vaccines and Immunization
 Devices, Vector Control).;
 2023. https://extranet.
 who.int/pqweb/vitrodiagnostics/collaborativeprocedure-acceleratedregistration
- 28. Subramanian L.
 Effective Demand
 Forecasting in Health
 Supply Chains: Emerging
 Trend, Enablers, and
 Blockers. Logistics.
 2021;5(1). doi:10.3390/
 logistics5010012

- 29. Iskandar K, Molinier L, Hallit S, et al. Drivers of antibiotic resistance transmission in low-and middle-income countries from a "one health" perspective—a review. Antibiotics. 2020;9(7):1-23. doi:10.3390/antibiotics9070372
- 30. Access to Medicine Foundation. Antimicrobial Resistance Benchmark 2021. Published online 2021.
- 31. Shionogi. Shionogi, GARDP and CHAI announce landmark license and collaboration agreements to treat bacterial infections by expanding access to cefiderocol in 135 countries. Published 2022. Accessed January 7, 2024. https://www.shionogi.com/global/en/news/2022/06/e220615.html
- 32. World Health Organization. Antimicrobial Stewardship: A competency-based approach. Published 2023. Accessed November 7, 2023. https://openwho.org/ courses/AMR-competency

ABOUT THE AMR INDUSTRY ALLIANCE

The AMR Industry Alliance is one of the largest private-sector coalitions established to provide sustainable solutions to curb antimicrobial resistance. The Alliance, comprised of 77 biotechnology, diagnostics, generics, and research-based pharmaceutical companies and 10 trade associations, facilitates collaboration, reports on the industry's contribution to the fight against AMR, and engages with external stakeholders. The Alliance seeks to contribute sustainable solutions to curb antimicrobial resistance by creating broad industry momentum and facilitating collaboration between the public and private sectors.

amrindustryalliance.org

