

AMR INDUSTRY ALLIANCE

Call-to-Action in the Fight Against AMR

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Introduction

Antimicrobial resistance (AMR) is a direct threat to global public health. In 2019 alone, it was estimated that nearly 5 million deaths were associated with resistant bacterial infections—1.27 million of which were directly attributable to AMR. 1,2 If we do not take steps to curb AMR, current antimicrobials, including both antibiotics and antifungals, will become ineffective against infections and infectious diseases and render routine medical procedures, such as hip replacements, cesarean sections, and root canals too risky to perform. Further, AMR is a major risk to vulnerable, immunocompromised patients, like those on chemotherapy or immunosuppressants, taking away an essential line of defense and turning back the clock on modern medicine as we know it. In addition to this significant public health problem, AMR also poses a societal problem that threatens the achievement of the Sustainable Development Goals by 2030.

Without immediate, focused, and coordinated actions to curb the spread of AMR, treating infections will become even more complex, and increasingly impossible. Representing members from across the life sciences industry, the AMR Industry Alliance uniquely understands the complexities of the AMR challenge and is committed to playing its part. We recognize that fighting AMR requires a broad, multistakeholder approach. This includes addressing market failures that threaten innovation toward new antimicrobials, the sustainability of supply chains, and reducing barriers to equitable access. We also recognize this collective approach is key to developing tools for prevention to reduce the burden of infectious disease such as adequate sanitation, hygiene, and uptake of vaccines—much like the broad approach taken by the UN at the 2023 high-level meetings on TB³ and universal health coverage (UHC)⁴ as well as the first High-Level Meeting on AMR in 2016.

We reaffirm that the 2030 agenda for the Sustainable Development Goals offers a framework to ensure healthy lives and promote well-being for all ages. The Sustainable Development Goals commit the UN and its Member States to act on global public health threats.

The private sector is a critical partner in setting the agenda and taking action against AMR. Current diagnostics and antimicrobials are key resources in the fight against AMR, and the appropriate utilization of what's available worldwide is as critical. Innovation of current and new antimicrobials is also needed to protect against emerging resistance.

Therefore, on the occasion of the second UN High-level Meeting on Antimicrobial Resistance in September 2024, the AMR Industry Alliance calls on the UN and its Member States to commit to and advance bold, coordinated action on AMR.

Antimicrobial treatments (e.g., antibiotics and antifungals) and infectious disease diagnostics have revolutionized medicine and reduced the risks of medical practices such as surgery⁶ and cancer care.^{7,8} Since their introduction, antimicrobials have been estimated to add an average of 23 years to global lifespans.⁹ Diagnostic tests have played a key role in enabling these gains as one of the tools that help medical professionals practice good stewardship and understand what treatments are appropriate for their patients. Together, these innovations are foundational to effective health systems—underscoring the importance of patient access to appropriate use of antimicrobials and diagnostics when needed.

Members of the AMR Industry Alliance—composed of biotech, diagnostics, generics, and research-based pharmaceutical companies and associations—are united in their efforts to find and advance sustainable solutions to curb AMR. The Alliance seeks to galvanize efforts across the life sciences sector and facilitate collaboration between the public and private sectors against this growing public health threat. Since its founding in 2017, the Alliance has taken action to address AMR based on its four core pillars.

The Alliance recognizes that we must work alongside governments, international organizations, academia, civil society, and other key stakeholders to take collective action to address AMR fully.

EXAMPLES OF ENGAGEMENT UNDER THESE FOUR PILLARS INCLUDE:



MANUFACTURING

The AMR Industry Alliance published its Antibiotic Manufacturing Standard in 2022 to help facilitate responsible manufacturing.¹⁰



RESEARCH & SCIENCE

Members of the AMR Industry Alliance have made investments in the development of new antimicrobials of approximately \$1.9 billion to \$2 billion annually in 2021 and 2022.¹¹



ACCESS

In 2019, the Alliance presented its report on Access Barriers,¹² followed by a followon study on barriers to a sustainable supply of off-patent antimicrobials in 2023,¹³ and an assessment of regulatory barriers to access for antibiotics,¹⁴ followed by its roadmap with actionable steps to tackle access barriers early in 2024.



APPROPRIATE USE

Since 2021, the Alliance has awarded the yearly Stewardship Prize to identify and recognize innovative approaches to combat AMR in low-to moderate-income countries.

AMR Industry Alliance Call-to-Action

In the lead-up to the High-level Meeting on AMR at the United Nations General Assembly in September 2024, the members of the AMR Industry Alliance call on the United Nations (UN) and its Member States to increase their efforts in the fight against AMR, to work with stakeholders in the public and private sectors to identify and prioritize risk-based solutions to drastically curb the spread of AMR, and to include them in the High-level Declaration on AMR, including:

- 1. Strengthen responsible manufacturing of antibiotics worldwide
- 2. Transform the antimicrobial ecosystem to ensure a functioning and sustainable market
- 3. Remove barriers to equitable antimicrobial access and enable a sustainable and robust global supply chain
- 4. Improve the appropriate use of antimicrobials through better valuation of and investment in diagnostics

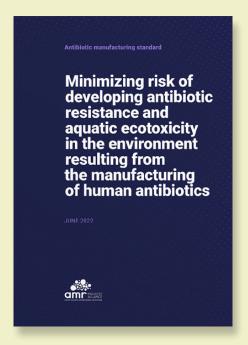


If not properly controlled, antibiotic manufacturing risks exacerbating AMR by releasing products or byproducts into the environment, potentially leading to aquatic ecotoxicity and antibiotic exposure. Antibiotic manufacturers must ensure effective control of antibiotic emissions from production processes into the environment to minimize the risk of AMR developing and spreading in the environment.

To facilitate responsible manufacturing, the AMR Industry Alliance published its **Antibiotic Manufacturing Standard** in 2022. ¹⁵ This Standard sets clear expectations for manufacturers in the global antibiotic supply chain to ensure that their antibiotics are made responsibly, helping to minimize the risk of AMR in the environment.

In 2023, the British Standards Institution (BSI) launched the first Minimized Risk of Antimicrobial Resistance certification, allowing companies to independently confirm that an antibiotic is made in accordance with the requirements of the Standard. The independent certification was designed to encourage antibiotic manufacturers and their supply chain partners to prioritize the sustainable production of antimicrobials. If the certification is broadly adopted, it will be a major step toward ensuring responsible antibiotic manufacturing worldwide.

Antibiotic Manufacturing Standard (2022)





The AMR Industry Alliance believes uptake of the Standard through independent certification is an essential step in ensuring that antibiotic manufacturing doesn't increase the risk of AMR development and will have positive impacts on Member States' health, environmental, and sustainability goals.

The AMR Industry Alliance calls on the UN and its Member States to adopt the Antibiotic Manufacturing Standard as part of their tendering and reimbursement policies. The AMR Industry Alliance also calls on the UN and its Member States to incentivize all antibiotic manufacturers and suppliers to be certified per the standard through third-party certification.

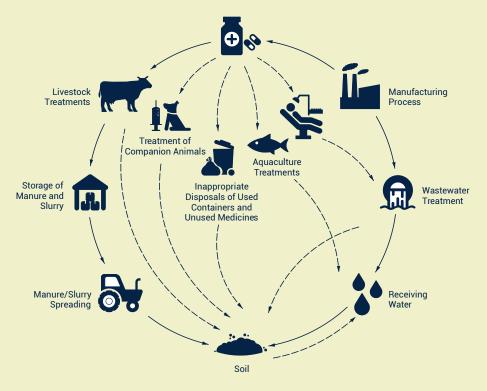


Predicted no-effect concentrations (PNECs) to target wastewater from antibiotic manufacturing

One of the first steps in creating the AMR Industry Alliance's Antibiotic Manufacturing Standard was the development and publication of predicted no-effect concentrations (PNECs) to serve as targets for wastewater effluent risk assessments.¹⁷

In 2018, following analysis and scientific discussion of the available data, the Alliance first published concentrations below which adverse environmental effects are not expected to occur (predicted no-effect concentrations, or PNECs) and now updates these annually. PNECs are specific to different types of antibiotics; currently, **PNECs are listed for 125 antibiotics**. For manufactured antibiotics that are not on the list, a statistical evaluation of currently available data was conducted, and a default PNEC of 0.05 µg/L was set for antibiotics in the absence of other data.

SOURCES OF ANTIMICROBIALS IN THE ENVIRONMENT



SOURCE: Antibiotic manufacturing standard, June 2022.



Continuous innovation is needed to stay ahead of evolving resistance. Despite the urgent need to deliver the next line of defense against bacterial infections, the development of new products has been decreasing and the pipeline for new antibiotics is recognized as insufficient. Since the early 1990s, an average of one new antimicrobial was approved per year, 18 and there are several high-profile cases in which the company launching the new antimicrobial eventually went bankrupt. 19,20,21 Additionally, many pharmaceutical companies are exiting the space.

As a result, antimicrobial innovation is waning, as shown, for example, by the difference in patents awarded for cancer treatments (2388) versus antimicrobials (115) in 2022, while the pipeline for oncology components contains over 2,000 products versus 80 products in the antimicrobials pipeline. Part of this decrease is due to the unsustainable market for antimicrobial products. The main reason is that payment systems still fail to value existing antimicrobials in accordance with their economic and societal value—or to take into account the value of offsetting the negative impact of AMR—which means these products don't generate sufficient revenues to attract investment into continued R&D or to maintain uninterrupted supply sustainably.

The need to transform the ecosystem has been acknowledged by the G7 every year since 2017, for example, committing to exploring and implementing push and pull incentives to accelerate R&D of antimicrobials in their 2023 Leaders Communique.²⁵ As of yet, only the United Kingdom is now implementing a permanent pull incentive.



AMR Industry Alliance in Action

Tracking the decline in AMR research professionals

A study by the AMR Industry Alliance in 2024 found that the number of AMR R&D-related researchers is declining.²⁶ Overall, there is an estimated number of 3,000 AMR researchers currently active in the world, compared to as many as 46,000 for cancer, as the number of deaths due to AMR continues to climb worldwide. These findings are supported by a CARB-X presentation during the 2023 World Health Summit highlighting that private sector researchers often leave the AMR field when companies go bankrupt or leave the space.²⁷

LEAVING THE LAB: TRACKING THE DECLINE IN AMR R&D PROFESSIONALS (2024)



The study's findings make it clear that unless prompt action is taken to ensure a sustainable ecosystem, the attrition in the R&D workforce will continue, leaving us unprepared to develop and advance new AMR medicines even if a package of incentives is implemented in the future.

While investment against AMR continues, it is trending downwards.²⁸ Importantly, it is insufficient in critical product development stages, resulting in a continued decline of the clinical antibiotic pipeline. Many stakeholders have recognized these innovation and availability challenges, leading to increased investment related to AMR. Focusing specifically on the R&D of new antimicrobial products, 34 members of the AMR Industry Alliance invest approximately \$2 billion annually.²⁹

Additionally, the private sector created the AMR Action Fund, which will invest \$1 billion to support the development of promising antimicrobial products while all stakeholders work toward a new incentive structure to keep the pipeline alive.³⁰ The AMR Action Fund raised an additional \$140 million from non-industry investors in 2021.³¹ However, the Fund will not solve the fundamental market challenges of antibiotic R&D for which new incentives are needed. Ultimately, private sector investments will only work if governments and other healthcare stakeholders create a more sustainable market for antimicrobial products.

More is needed in the form of market-based incentives to drive antimicrobial R&D and encourage researchers and medical specialists to stay dedicated to this critical area of medicine. Beyond these incentives, measures are required to address the growing shortage of researchers and medical specialists dedicated to this critical area of medicine.

The AMR Industry Alliance calls on the UN and its Member States to transform the market for antimicrobials with new incentives that encourage companies, investors, and researchers to pursue ongoing antimicrobial innovation and market launch.



To slow the spread of AMR, patients must have access to quality-assured antimicrobials when needed. Surveys by the WHO and other groups suggest that sustainable availability of antimicrobials (both novel and generic) is a worldwide challenge. 32,33,34,35 The problem of availability and access is especially critical in low- and middle-income countries (LMICs), where most of the 5.7 million people dying from antimicrobial resistance are from. 36

Antimicrobial supply chains must operate smoothly. But in many parts of the world, the supply chain is unstable, leading to limited—and therefore inequitable—antimicrobial access for patients who need them.

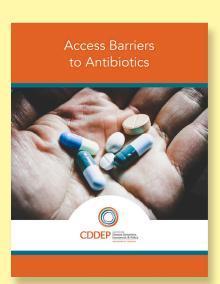


Addressing access barriers

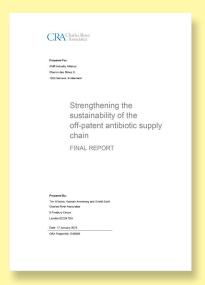
The Alliance has examined the issue of access with its 2019 Access Report, ³⁸ a 2022 assessment of regulatory barriers to access for antimicrobials, ³⁹ and a study on barriers to a sustainable supply of off-patent antimicrobials in 2023. ^{37,40} Barriers to antimicrobial access include the complexity of regulatory systems; antimicrobial prices that are set too low to recoup manufacturing, supply, and other costs; supply chain instability and logistical issues; and demand predictability. The 2023 report found that there are many instances where manufacturers faced difficulties in supplying enough antimicrobials to specific countries due to procurement practices.

These policies and practices, particularly for generic antimicrobials, can drive the prices of all products down to the point where the price of any antimicrobial is too low to allow for its continued manufacturing and supply to the market. They can also lead to supplier consolidation (for finished products and API), which increases the risk of shortages and stockouts.⁴¹ Therefore, it is important that governments consider pricing approaches that recognize the value of antimicrobials—both on and off-patent.

THE ALLIANCE'S RESEARCH REPORTS ON ACCESS BARRIERS (2019, 2022 and 2023)

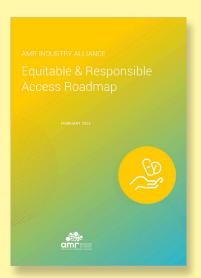






In 2024, the AMR Industry Alliance released its **Equitable & Responsible Access Roadmap** to outline steps that can be taken to tackle the barriers of regulatory issues, demand forecasting, and procurement challenges.

EQUITABLE & RESPONSIBLE ACCESS ROADMAP (2024)



Key takeaways on access barriers include:

- Countries with fewer resources for the registration of antimicrobials should consider working with the WHO on the collaborative procedure for accelerated registration of pregualified finished pharmaceutical products.⁴²
- Improving health data infrastructure, resistance, and antimicrobial consumption surveillance systems can help monitor demand and improve forecasting.⁴³ Governments and the private sector should work together toward strengthening data infrastructure.

Several possible solutions exist to improve the market and economic ecosystem for antimicrobial products. Recent policy briefs and pilot reimbursement programs have recommended subscription models that encourage antimicrobial access by providing a predictable revenue stream. In addition, novel approaches to antimicrobial procurement that reimburse based on the value the product provides and pooled procurement agreements may facilitate more sustainable supply and increase availability.

Finally, public-private partnerships like the collaboration between the Global Antibiotic Research & Development Partnership (GARDP), the Clinton Health Access Initiative (CHAI), and Shionogi—creating the first licensing agreement between a pharmaceutical company and a non-profit organization—provide insight into possible solutions.⁴⁴

Mitigating access barriers requires a multi-stakeholder approach where governments, the private sector, multilateral organizations, healthcare professionals, and civil society work together. Governments can take essential steps to lead this process by focusing on those barriers that disincentivize market entry and by addressing issues that would improve the sustainability of the antimicrobial supply chain.

The AMR Industry Alliance calls on the UN and its Member States to take actionable steps to ensure equitable access to antimicrobials around the world by removing barriers to registration, accelerating approvals, improving forecasting through better data collection and surveillance, and reforming antimicrobial procurement practices.



Appropriate prescribing of antimicrobials by physicians is critical for patient safety and drug effectiveness and is vital for stemming the emergence of AMR. Tools like the WHO AWaRe handbook and antimicrobial stewardship protocols can help to guide appropriate prescribing and use. However, diagnostic tests are foundational for understanding the type of infection and, therefore, the best course of treatment.

To help improve prescribing and promote stewardship worldwide, the World Health Organization (WHO) developed the AWaRe (Access, Watch, and Reserve) classification system for antibiotics. The classification organizes antibiotics into "Access," "Watch," and "Reserve" groups and suggests combinations of antibiotics that should not be used together in clinical practice.

ACCESS

Access antibiotics have a narrow spectrum of activity, lower cost, a good safety profile, and generally low resistance potential. They are often recommended as empiric first- or second-choice treatment options for common infections.

WATCH

Watch antibiotics are broader-spectrum antibiotics, generally with higher costs, and are recommended only as first-choice options for patients with more severe clinical presentations or for infections where the causative pathogens are more likely to be resistant to Access antibiotics, such as upper urinary tract infections (UTIs).

RESERVE

Reserve antibiotics are the last-choice antibiotics used to treat multidrug-resistant infections.

To encourage appropriate use, the WHO has set a target calling for 60% of global antibiotic consumption to be Access group antibiotics in 2023.⁴⁵ A 2021 examination of sales data from 76 countries from 2000 to 2015 found that 45% (42 out of 76 countries) were not achieving this goal.⁴⁶

Diagnostic tests play a critical role in the fight to reduce AMR. Diagnostic tests have the potential to aid in the detection of specific pathogens, discovery of new pathogens, determination of appropriate therapy, monitoring response to therapy, assessment of prognosis, and disease surveillance. Diagnostic tests are crucial for treating patients appropriately and preventing the development and spread of AMR. Diagnostic tests can help clinicians decide which specific drug will work best, reducing the risk of inappropriate antimicrobial use and improving patient care. Evidencebased diagnostic tests and antimicrobial stewardship (AMS) programs should inform the appropriate use of antimicrobials. Barriers to accessing and using diagnostics diminish the effectiveness of AMS programs and should be addressed and an effort should be made to establish consensus on meaningful and feasible AMS metrics to track progress.



The Stewardship Prize

Through its **Stewardship Prize initiative**, the AMR Industry Alliance aims to recognize established, innovative approaches to antimicrobial stewardship in LMICs and inspire other organizations to learn from these successes.⁴⁷

In 2023, the Stewardship Prize was awarded to Stellenbosch University/ Tygerberg Hospital in South Africa for their NeoAMS program, which targets inappropriate antibiotic use among hospitalized newborns. The neonatal period is the most vulnerable period in a child's life. Launched in 2022, the NeoAMS program trains local clinicians on best practices of neonatal antibiotic stewardship (AMS) by assembling neonatal AMS teams, facilitating interactive online AMS training, and supporting audits and feedback on antibiotic prescriptions for hospitalized neonates. The program encourages regular interaction between site teams, including pharmacists, neonatologists, microbiologists, and neonatal unit nurses.

In previous years, the prize was awarded to Lekma Hospital in Ghana,⁴⁸ Pakistan's Clinical Engagement Program,⁴⁹ and the Infectious Diseases Institute (IDI) in Kampala, Uganda.⁵⁰

Timely use of diagnostic tests can determine if the cause of an illness is due to an infection and what antimicrobials would be best to treat the infection. Despite dramatic advances in diagnostic technologies, many patients with suspected infections receive empiric antimicrobial therapy rather than therapy dictated by the rapid identification of the infectious agent. Empiric antimicrobial therapy can lead to the overuse of antimicrobials.

Regulatory authorities have approved many safe and effective diagnostic tests available to healthcare professionals today. Unfortunately, in many countries, access to diagnostics is limited.⁵¹ Research suggests that nearly half (47%) of the people in the world have little or no access to diagnostic tests.⁵² As a result, it is estimated that between 30% and 50% of antimicrobials prescribed to humans may be inappropriate.⁵³

Diagnostics improve the quality of care, promote wellness, and often reduce healthcare costs. However, many diagnostic tests are not being fully utilized in healthcare systems around the world, impeding their efficacy in support of several challenges to appropriate antimicrobial use. There needs to be improved education regarding the utility of diagnostic tests and the value they provide when integrated into healthcare protocols. Finally, many countries have inadequate infrastructure to leverage diagnostic testing, even if it is available.



Minimizing barriers to antimicrobial diagnostics

In 2024, the AMR Industry Alliance presented its **Equitable & Responsible Access Roadmap** to outline steps that can be taken to tackle the barriers of diagnostics infrastructure, test valuation, and funding.⁵⁴ Key takeaways on appropriate use include:

- Research shows that laboratory infrastructure is inadequate in many LMICs.⁵⁵ Countries should prioritize investments in laboratory infrastructure improvements for the use of diagnostic tests to improve health system sustainability and resilience.
- In cases where the value of testing is not recognized, there is no demand for further investments in testing. Countries should improve reimbursement decisions for diagnostic tests in consideration of both the short-term value they bring to patients and the long-term value they bring to healthcare systems in the form of cost savings and lower resistance rates.

Even when diagnostic tests are approved, infrastructure must be in place to collect samples and deliver results. Information learned from a diagnostic test can also contribute to and support local, national, and global AMR surveillance efforts. AMR surveillance is important for understanding regional resistance patterns, how resistance might be evolving, and what type of antimicrobial products might be needed now and in the future. Broad surveillance efforts can help inform prescribing, and government and health systems should work to strengthen the surveillance network and data-sharing resources.

The AMR Industry Alliance calls on the UN and its Member States to improve the appropriate use of antimicrobials by utilizing diagnostic tests and implementing stewardship programs, prioritizing investments in laboratory infrastructure, improving the valuation of diagnostics based on their short- and long-term value, expanding surveillance of AMR at the local, national, and global levels, and establishing consensus on meaningful and feasible AMS metrics to track progress.

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 stakeholders and policymakers. 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.

The Alliance, in its diversity of membership incorporating the full spectrum of life sciences companies and associations, serves as a unique industry voice and facilitator of industry progress. It produces annual reports on its activities and the activities of its members and drives progress through its working groups on access, appropriate use, research and science, and manufacturing.

Since its inception in 2017, the AMR Industry Alliance has established itself as a key private sector partner in combating AMR, fostering collaboration among its members, and partnering with countless public and private sector entities to push progress on AMR. The Alliance ensures a collective voice on behalf of the industry to inform ongoing discussions around achieving the Sustainable Development Goals by the UN, the importance of AMR to the UN's 2030 Agenda, and the steps to implement the political declaration from the 2016 UN High-level Meeting on AMR.



Industry commitments to combating AMR

The AMR Industry Alliance was launched in May 2017, following two declarations of industry commitments to address AMR: the January 2016 "Declaration by the Pharmaceutical, Biotechnology, and Diagnostics Industries on Combating Antimicrobial Resistance" and, at the first UN High-level Meeting on AMR in September 2016, the "Industry Roadmap for Progress on Combating Antimicrobial Resistance." 57

The Alliance ensures that signatories from biotech, diagnostics, generics, and research-based pharmaceutical companies collectively deliver on the specific commitments made in the Declaration and the Roadmap and will measure progress made in the fight against AMR. The Alliance unified its commitments in the four pillars of manufacturing, R&D, access, and appropriate use.⁵⁸

On appropriate use, signatories committed to furthering the use of antimicrobials only in patients who need them through:

- Supporting governments and public health work to educate healthcare
 professionals and patients on appropriate use and the value of vaccination as
 a cost-effective preventative intervention that complements good stewardship
 through expanded use of diagnostics.
- Assessing promotional activities to ensure they align with good stewardship and eliminating those that do not preserve existing antimicrobials through correct use.
- Continued sharing of surveillance data with public health bodies and healthcare
 professionals along with partnership with them to improve the understanding
 of resistance trends and appropriate antimicrobial and vaccine use, thus
 increasing surveillance capacities globally.
- Working directly with governments, their agencies, and other stakeholders to reduce uncontrolled antimicrobial purchases, such as over the counter and non-prescription internet sales.

On manufacturing, signatories committed to reducing the environmental impact of the production of antimicrobials by:

- Reviewing members' own manufacturing and supply chains to assess good practices in controlling releases of antimicrobials into the environment.
- Establishing a common framework for managing antibiotic discharge.
- Working with stakeholders to develop a practical mechanism to demonstrate supply chain standard compliance.
- Developing science-driven, risk-based targets for discharge concentrations for antimicrobials and good practice methods to reduce the environmental impact of manufacturing discharges in partnership with independent technical experts.

Commitments to improved access alongside appropriate use included:

- Working with international bodies, governments, and other stakeholders to
 identify and address access, market sustainability, and supply bottlenecks for
 existing antimicrobials, diagnostics, and vaccines and developing innovative
 financing and procurement mechanisms to resolve them.
- Establishing new business models with stakeholders to improve access to new antimicrobials, diagnostics, and vaccines globally while supporting appropriate use.
- Seeking to accelerate the introduction of processes, technologies, and regulations required to reduce the prevalence of substandard or counterfeit antimicrobials in high-risk markets.

Finally, the Alliance committed to open collaboration among industry and public researchers to overcome the scientific challenges of the creation of new antimicrobials, vaccines, and diagnostics, and committed specifically to:

- Progress incentives, such as lump-sum payments, insurance models, and novel IP mechanisms to reflect the societal value of new antimicrobials and vaccines and attract further investment in research and development.
- Exploring opportunities to address key scientific challenges through further pre-competitive collaboration, building on experience with the TB Accelerator, IMI, and GHIT.
- Supporting the creation of open and sustainable clinical trial networks globally
 with the Alliance's expertise and experience to build on work started in Europe
 and the US to improve the speed and efficiency of clinical trials.
- Engaging with stakeholders to facilitate data exchange on marketed antimicrobials to fill specific gaps in the global pipeline.

Industry progress in the fight against AMR

Since its launch in 2017, the AMR Industry Alliance has fulfilled and continues to pursue these commitments. For example, the Alliance launched the Common Antibiotic Manufacturing Framework in 2018 and published its list of antibiotic manufacturing discharge targets (predicted no-effect concentration—PNEC) in September 2018 and has since updated these targets.

Building upon the Framework, the Alliance released its manufacturing standard in 2022. It has utilized the independent, non-profit British Standards Institution since 2023 to provide a certification program for member and non-member manufacturers who comply with the Standard.⁵⁹

Alliance members also continue to engage in research and development (R&D), investing \$1.9 to \$2 billion annually in 2021 and 2022,⁶⁰ according to the Alliance's 2023 Progress Report.

The majority of the surveyed Alliance members engaged in collaborative R&D activities, reflecting Alliance members' commitment to collaboration in the fight against AMR. The most common partnerships were with other private sector organizations (85%), but over two-thirds of responding R&D active companies also reported partnerships with country-level government bodies and academic institutions (68%). Over half (53%) collaborated with other types of organizations, for example, not-for-profits, public-private partnerships, and international AMR-focused initiatives or networks.⁶¹

Unfortunately, Alliance members also reported significant challenges in the survey for the 2023 progress report, which affected their decisions on whether and how much to invest. These challenges include market viability concerns, a lack of appropriate pull incentives/instruments, a lack of proper push incentives, and the high cost of the regulatory approval process.⁶²



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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.

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