



AMR INDUSTRY ALLIANCE

2022 Year In Review



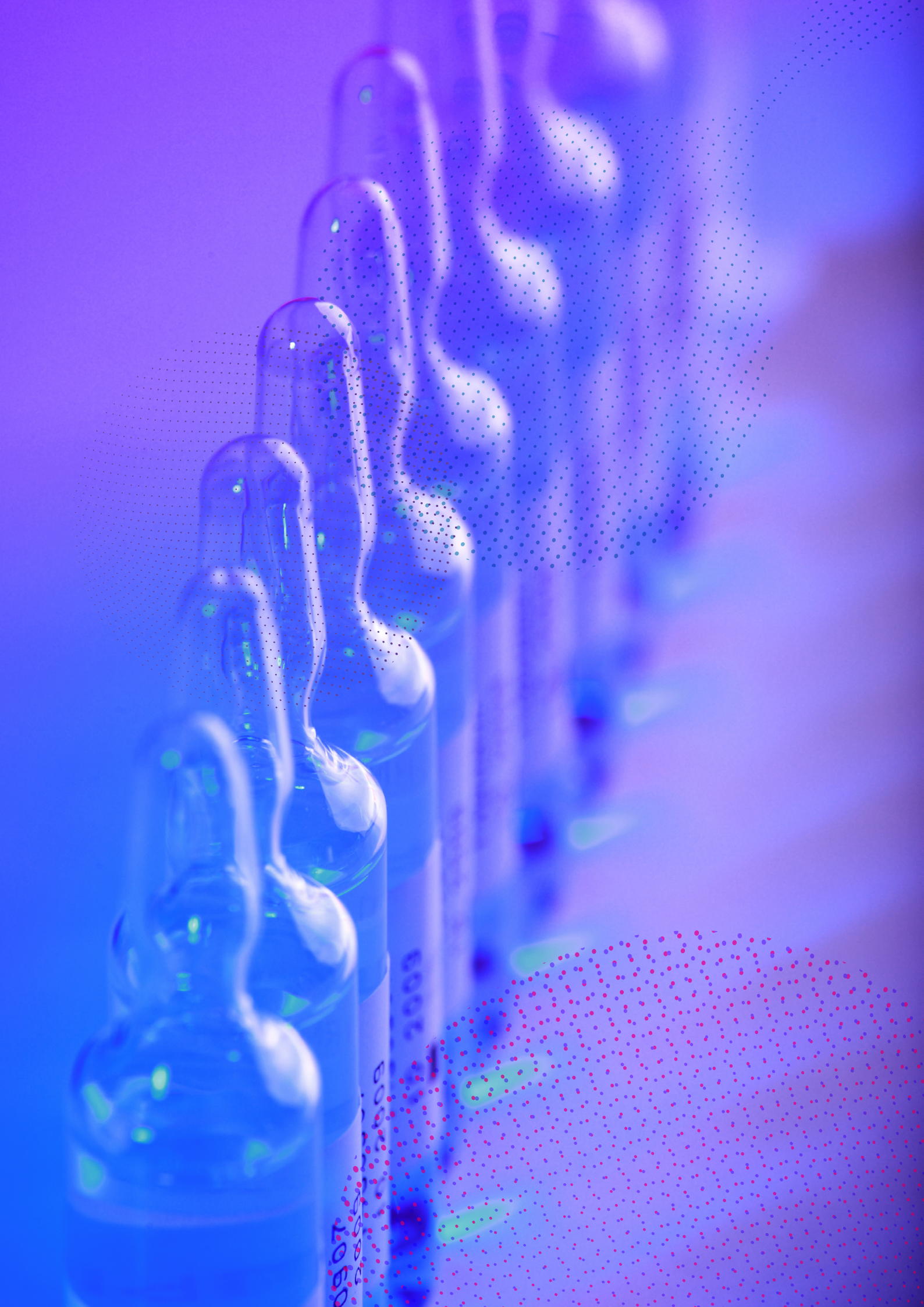
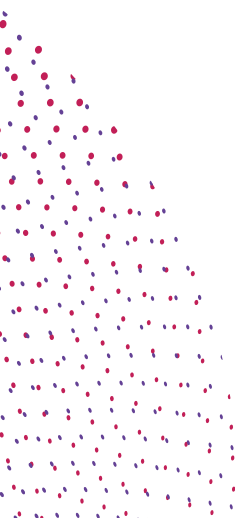


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Letter from the Chair

As the new Board Chair of the AMR Industry Alliance, it is my pleasure to share this 2022 review with our members and key stakeholders across the AMR landscape. As the largest life-sciences coalition of its kind – representing a cross-section of biotechnology, diagnostic, generics, and research-based biopharmaceutical companies and trade associations – the AMR Industry Alliance has been setting the pace for how organizations, private and public, can and should be working together to provide sustainable solutions to curb antimicrobial resistance.

Antibiotics are essential innovations that have revolutionized modern health-care. Unchecked, AMR threatens to undermine the basis of modern medicine by rendering the antibiotics used to treat and prevent infections ineffective. AMR is now considered a top ten global public health threat, according to the World Health Organization (WHO). AMR Industry Alliance members remain committed to the fight against AMR, stepping up to access challenges, implementing appropriate use and stewardship activities, supporting innovation toward new antibiotics and working to mitigate the impact of antibiotic manufacturing in the environment. As this report shows, we can be proud of the achievements made across these four areas of work, with the Alliance generating substantial evidence and data to support the development of solutions. For instance, among other initiatives, in 2022, the Alliance launched our *Antibiotic Manufacturing Standard*, released reports on supply chain stability and antimicrobial innovation, and continued to highlight and support exceptional work on the fight against AMR around the world through our annual AMR Stewardship Prize.

When the Alliance was founded in 2017, we committed to sharing details of our collective industry-led progress on AMR, and over the past six years, that has been reflected in our biennial surveys and *Progress Reports*. This 2022 review separates our survey work, which we will continue to publish separately, from our overview of achievements, which will be reported annually from now on. Progress to tackle AMR is happening, but even with heightened awareness and powerful data, we still need more coordinated action among stakeholders. I look forward to continuing these efforts in 2023 in collaboration with our members and all external stakeholders that share our dedication to fighting AMR.

James Anderson, Chair, AMR Industry Alliance

AMR Industry Alliance Members



MeijiMeMedMENARINI
groupMERCKMICROBION
CORPORATION
biosciences | industriesmodernaMSDMUTABILISNabriya
THERAPEUTICSNAICONSNorthern
AntibioticsNosopharm
First-in-class Anti-InfectivesNovaBioticsNOVARTISORAGENICSOtsukaPARATEKPeptilogicsPfizerPHARE BIOPHERECYDES
PHARMARebiotix
Microbiota Restoration Therapy
A FERRING COMPANYsanofiSCYNEXISSHIONOGISinSavalSOLIGENIXSPERO
THERAPEUTICSSPEXISSumitomo
PharmaSummit
therapeuticsTAXIS
Pharmaceuticals, Inc.tevaBIA
UK BioIndustry AssociationUNION
THERAPEUTICSVenatorx
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Enjoy InnovationsVIATRISVibiosphen
Host defense research and innovationxellia
PHARMACEUTICALS

Introduction

AMR is a dire public health threat. In 2019, an estimated 4.95 million people died suffering from at least one drug resistant infection, and 1.27 million of those deaths were directly caused by AMR.¹ Antibiotics are becoming increasingly less effective and few new antibiotics are available to replace them. Improper use of antibiotics, research and development pipeline challenges, inadequate sanitation, and issues in the environment and agricultural sectors all contribute to AMR and its risks. Due to these many contributing and complex factors, it is imperative to address AMR as a global public health issue with the collaboration and focus of cross-sector stakeholders in both public and private sectors.

The AMR Industry Alliance, as the largest life-sciences coalition of its kind, is leading the way in advocacy and action on AMR and collaborating with public and private entities to affect policy and practices.

The AMR Industry Alliance was established in 2017 to provide sustainable solutions to curb AMR. Its more than 100 members, consisting of biotech, diagnostics, generics, and research-based pharmaceutical companies and associations, collaborate to measure and drive industry progress on AMR. Working together, the Alliance increases accountability and facilitates progress by breaking down traditional silos across the life sciences industry through information sharing.

2022 AMR Industry Alliance Timeline of Key Milestones



ALLIANCE FOCUS AREAS



Alliance Focus Areas

The AMR Industry Alliance structures its work around four major focus areas: Access, Appropriate Use, Manufacturing, and Research and Science. Within each of these areas, the Alliance brings together leaders across the life sciences industry to collaboratively advance the dialogue on AMR and develop sustainable solutions focused on engagement, advocacy, and action to combat AMR.

In 2022, the Alliance led initiatives across all four areas to both advance the global dialogue on these topics and to promote a common agenda among private-sector stakeholders part of the AMR Industry Alliance.

This 2022 review details these initiatives as a framework for engagement among Alliance members and all global stakeholders engaged in tackling AMR.



ACCESS

Access to quality antibiotics and ensuring new ones are available to all, and improve and accelerate access to diagnostics in low- and middle-income countries



APPROPRIATE USE

Appropriate use of antibiotics to reduce the development of AMR with the support of vaccines and diagnostics



MANUFACTURING

Manufacturing to mitigate environmental impact and advance responsible manufacturing through standard setting



RESEARCH & SCIENCE

Research and science to meet public health needs with new innovative diagnostics and treatments

2022 ALLIANCE INITIATIVES:

Access Framework for LMIC Hospitals

Report:
Strengthening the Sustainability of the Off-Patent Antibiotic Supply Chain

2022 AMR Stewardship Prize: Strengthening Stewardship and Appropriate Use in Low- and Middle-Income Countries

Value of Diagnostics Survey and Report

Infection Prevention and Stewardship for Sanitation Service Providers

Default Predicted No-Effect Concentrations Guidelines

Antibiotic Manufacturing Standard

Report:
Drug Regulatory Approvals and Opportunities for Antimicrobial Innovation – Perspectives from Brazil, India and South Africa

Access

Working to remove
barriers to equitable
access to antibiotics
around the world





2022 ALLIANCE ACCESS ACTIONS:

Access Framework for LMIC Hospitals

Report: *Strengthening the Sustainability of the Off-Patent Antibiotic Supply Chain*

AMR Industry Alliance Commitments in 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.

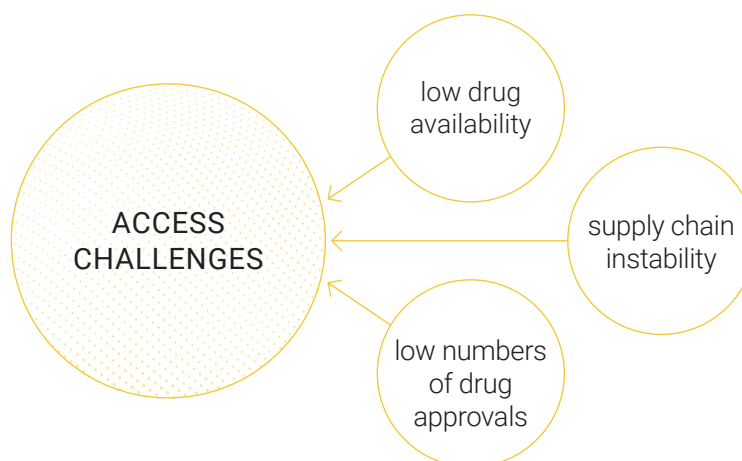
Work to reduce the prevalence of substandard and falsified AMR-relevant products.

It is crucial that patients have access to the right antimicrobials and diagnostics at the right times to save lives and prevent the spread of antimicrobial resistance.

When recommended antimicrobials and diagnostics are not available, doctors may end up prescribing alternative treatments that do not completely eliminate the pathogens affecting the patient, allowing resistance to develop and grow. Access is an issue across the world, with research suggesting that in some low- and middle-income countries, essential antimicrobials may be unavailable at as many as half of the healthcare facilities that need them.² High income countries also face a variety of access issues, including supply chain instability and low numbers of drug approvals, with some approving as few as two new antimicrobials in the past decade.^{3,4}

The AMR Industry Alliance has made commitments to improving access to antimicrobials and diagnostics across the world, and members are rising to the challenges of this issue through individual and collaborative activities that attempt to address its root causes in low-, middle-, and high-income countries. Alliance activities in relation to access to antimicrobials across 2022 are detailed below.

ANTIMICROBIALS ACCESS CHALLENGES



Access Framework for LMIC Hospitals

LMICs face a variety of challenges in ensuring access to antimicrobials and diagnostics, ranging from regulatory issues at a country-level, to issues related to availability and use at a local level. Key stakeholders such as the World Health Organization (WHO) are working to assess and improve the procurement and delivery of antibiotics and diagnostics at a high-level, focusing on regulatory issues and harmonization. To complement those existing efforts, the Alliance has focused its work around ways to improve the delivery of antimicrobials and diagnostics to regions and hospitals once they are available in each country. To that end, in 2022, the Alliance, in partnership with Mann Global Health, developed an access framework intended to determine the feasibility of targeted pilots to further access in LMICs. The framework includes the process required to determine where and how best to create a targeted pilot. It also includes examples of the type of questions that would be used to assess an access program. The framework provides insight on action items for hospitals and enables collaboration and information gathering from external stakeholders. This work will serve as the foundation for future work on access within the Alliance.

Report: Strengthening the Sustainability of the Off-Patent Antibiotic Supply Chain

It is vital to secure a steady supply of off-patent antibiotics, which are essential to patient care. Challenges to the supply chain across high-, middle-, and low-income countries have resulted in global shortages of key antibiotics. To establish greater clarity on the root causes of global supply chain unsustainability, the Alliance commissioned Charles River Associates to develop a report to identify levers that can improve access and the sustainability of the off-patent supply chain. The report focuses on the off-patent market environment in Brazil, Germany, India, Vietnam, and South Africa. Through this initiative, Charles River Associates identified five areas of weakness in the global supply chain:

FIVE AREAS OF WEAKNESS IN THE GLOBAL SUPPLY CHAIN:

- | | |
|---|--|
| 1 | Difficulty in the production of generic antibiotics. |
| 2 | Unpredictable demand due to lack of efficient surveillance and diagnostics in LMICs. |
| 3 | Low commercial returns across the supply chain, from raw materials through to finished products. |
| 4 | Few off-patent suppliers remain globally due to poor commercial situations. |
| 5 | Inefficiencies in supply chain management, distribution, and communication. |
-

The report identified six of the highest priority solutions with potential to provide the most effective results:





































SIX PRIORITY SOLUTIONS FOR THE GLOBAL SUPPLY CHAIN:

| | |
|---|---|
| 1 | Pricing approaches to recognize the value of off-patent drugs. |
| 2 | De-linked subscription payment models. |
| 3 | Sustainable tender policies requiring supply security and multiple winners. |
| 4 | Reducing financial disincentives to market entry. |
| 5 | Improving forecasting through better use of diagnostic and surveillance data. |
| 6 | Better communication with supply chain structures. |

Through case study research, and interviews, the report identifies the way that supply chain challenges will manifest differently in countries depending on income level and geo-political situation. Therefore, the solutions provided need to be tailored to the country or region they are being applied to.

The key findings of the report were shared during World Antimicrobial Awareness Week (WAAW), as part of a webinar titled *Multi-Sectoral Approaches to Responsible Access: Working Together to Fight AMR*, which the AMR Industry Alliance led, along with speakers from the WHO, Wellcome Trust, Clinton Health Access Initiative and member companies BD and Viatrix. This webinar also addressed promising new strategies for addressing access in low- and middle-income countries and the role of diagnostics in the appropriate use of antibiotics. The final report, *Strengthening the Sustainability of the Off-Patent Antibiotic Supply Chain*, was published in early 2023.

SUMMARY OF ROOT CAUSES OF SUPPLY CHAIN UNSUSTAINABILITY ACROSS COUNTRIES

| CAUSE |  BRAZIL |  GERMANY |  INDIA |  VIETNAM |  SOUTH AFRICA |
|--|---|---|---|---|--|
|  Fragility of supply chain and manufacturing issues |  |  |  |  |  |
|  Low and unpredictable demand |  |  |  |  |  |
|  Commercial returns |  |  |  |  |  |
|  Concentration of API suppliers |  |  |  |  |  |
|  Poor supply chain management |  |  |  |  |  |
| LOW  → HIGH  | | | | | |

NOTE: Low importance indicates that the root cause has a low impact on the sustainability of the supply chain. High importance indicates that the root cause has a significant impact on the sustainability of the supply chain.



The use of antibiotics without a diagnostic often results in patients receiving an antibiotic treatment when they actually do not have a bacterial infection in the first place. There can be value gains to the healthcare system when appropriate treatments are done and there are better outcomes for the patient when they are better treated. The role of diagnostic stewardship in treatment is multi-fold. There is an additional benefit here, which is the capturing of information on the type of infections that people are suffering from and whether or not they are drug-resistant. This is quite important to guide public health interventions and actions and priorities.

Tim Jinks, Head of Interventions,
Wellcome Trust



It's important to link access, diagnosis, and stewardship together. While there have been major donor investments in HIV, TB, and malaria diagnosis and treatment delivery, there has not been major investment in diagnosis and treatment of bacterial infections by multilateral donors. That means that the products being developed with considerable resources... are being delivered into a vacuum, expanding the burden of stewardship onto an already challenging requirement to ensure access of their new products by originators. Ultimately a functioning market would link the cost of diagnostics and treatment in a manner that reinforces appropriate usage of products.

Dave Ripin, Executive Vice President of
Infectious Disease and Chief Science Officer,
Clinton Health Access Initiative (CHAI)

WEBINAR ON THE KEY REPORT FINDINGS

WORLD
ANTIMICROBIAL
 AWARENESS WEEK
 18-24 NOVEMBER

Multi-Sectoral Approaches to Responsible Access: Working Together to Fight AMR

James Anderson
AMRIA Board Chair

Valeria Gigante
Team Lead, AMR Division, WHO

David Ripin
EVP of Infectious Disease and
Chief Science Officer, CHAI

Erika Satterwhite
Head of Global Policy, Viatris and
AMR Industry Alliance Board Member

Tim Jinks
Head of Interventions, Wellcome Trust

Diane Flayhart
Global Program Leader, AMR, BD

A photograph of a female pharmacist with long blonde hair, wearing a white lab coat over a patterned top, smiling and talking to a patient. The patient has dark hair and is wearing a yellow and blue striped sweater. They are in a pharmacy setting with shelves of medicine in the background. A large teal speech bubble is overlaid on the bottom left of the image.

Appropriate Use

Promoting awareness and stewardship in the use of antibiotics



2022 ALLIANCE APPROPRIATE USE ACTIONS:

2022 AMR Stewardship Prize: Strengthening Stewardship and Appropriate Use in Low- and Middle-Income Countries

Value of Diagnostics Survey and Report

Infection Prevention and Stewardship for Sanitation Service Providers

AMR Industry Alliance Commitments in Appropriate Use

Contribute to slowing emergent resistance by preventing infections through vaccination promotion and reducing the inappropriate use of antibiotics via the expanded use of diagnostics.

Support the appropriate use of antibiotics by working closely with other partners on awareness campaigns, continued education for healthcare professionals and generation of evidence to support appropriate use and stewardship.

Collect and share surveillance data with public health bodies and healthcare professionals to improve understanding of resistance trends, monitor the effectiveness of antibiotics, inform appropriate antibiotic and vaccine use and develop adapted infection control strategies.

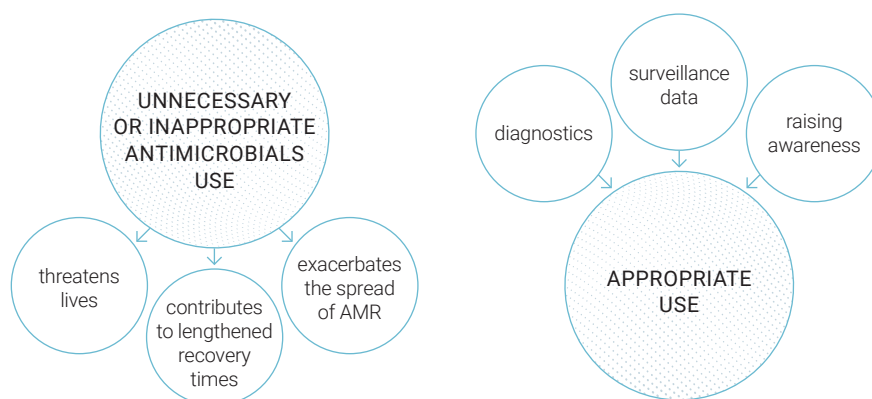
Ensure that any promotional activities for antibiotics align with the goal of advancing stewardship.

Research suggests that at least half of antimicrobials prescribed across the world are unnecessary or inappropriate.⁵ This is a serious problem that threatens lives, contributes to lengthened recovery times, and exacerbates the spread of AMR. Conversely, when antimicrobials are used appropriately, fewer pathogens develop resistance, and the effectiveness of commonly used antimicrobials is prolonged.

There are many actions that can be taken to encourage appropriate use. The active utilization of diagnostics helps medical professionals determine which treatments are truly needed. Surveillance data, and the use of that data to increase awareness about AMR and antimicrobial stewardship, can also contribute greatly to preventing inappropriate use.

Appropriate use is a priority for the Alliance, with 80% of members implementing stewardship strategies to help make individual impact on this problem. As an Alliance, collaborative initiatives are also being undertaken to address four commitments on this topic. The AMR Industry Alliance is partnering with other stakeholders to build awareness about appropriate use, bolster surveillance systems, and develop new diagnostic tools.

APPROPRIATE USE EFFECTS AND SOLUTIONS





STEWARDSHIP PRIZE ANNOUNCEMENT

2022 AMR Stewardship Prize: Strengthening Stewardship and Appropriate Use in Low- and Middle-Income Countries

The Alliance's annual Stewardship Prize is given to recognize innovative, scalable approaches to AMR stewardship in low- and middle-income countries. After an open application process and careful evaluation by the Alliance's Appropriate Use Working Group, the Alliance selected Lekma Hospital in Ghana and the Clinical Engagement Program in Pakistan as the winners of the 2022 AMR Stewardship Prize.

Value of Diagnostics Survey and Report

AMR Industry Alliance, along with member companies BD, Pfizer, and bioMérieux, are working in collaboration with Wellcome Trust to develop a report on the role of diagnostics in improving antimicrobial stewardship program effectiveness. This report is based on data collected through a multinational survey that Wellcome conducted. It evaluates the current state of diagnostics, the impact of diagnostic testing on patients and health systems, barriers to diagnostic usage, and recommendations for increased diagnostics uptake in the fight against AMR. The report will be released publicly in spring of 2023.

Infection Prevention and Stewardship for Sanitation Service Providers

In 2022, the Alliance initiated a collaborative project with the Toilet Board Coalition (TBC) to raise awareness of the importance of sanitation in tackling the spread of infectious and resistant infectious diseases. Together they are working to develop educational materials and recommendations on infection prevention and stewardship that sanitation service providers can easily adapt to local languages and use throughout their operations. Founded in 2015, TBC accelerates business solutions to the global sanitation crisis. TBC facilitates partnerships between and among small and medium-sized enterprises (SMEs), corporations, NGOs, investors and governments who share a commitment to achieve access to sanitation and hygiene for all by 2030. The TBC-Alliance program will roll out in fall 2023.

AMR Industry Alliance +



AMR Industry Alliance +



STEWARDSHIP PRIZE WINNER

Lekma Hospital, Ghana

Lekma Hospital, located in the city of Teshie in Ghana, noticed a high rate of self-medication amongst patients, which was leading to increased rates of antimicrobial resistance. To address this, Lekma established an AMR surveillance project focused on laboratory and pharmacy surveillance, an awareness campaign drive to promote antimicrobial stewardship, as well as training for clinical staff and community pharmacists. The hospital also included AMR surveillance and training in its Five-Year Strategic Plan and made it a core component of its Drug and Therapeutic Committee.

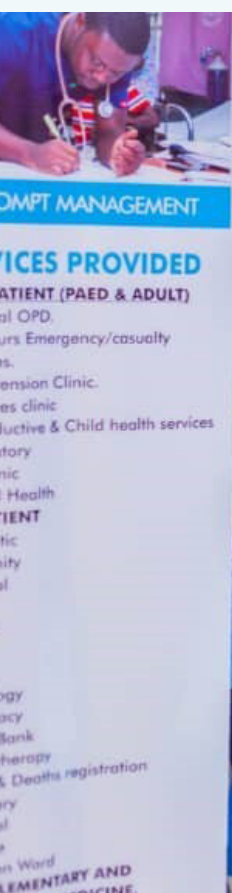
Since 2021, Lekma Hospital has worked to:

- Utilize joint, multi-disciplinary ward rounds to include doctors, nurses, and pharmacists.
- Implement identification and susceptibility testing for patients presenting with infectious diseases.
- Hold monthly reviews of rational use of antibiotics.
- Audit prescription at the wards and the outpatient departments
- Run antimicrobial stewardship/AMR awareness campaigns with the hospital and community.
- Train all hospital clinical staff and community pharmacists on antimicrobial stewardship/AMR.



Winning the AMR Industry Alliance Stewardship Prize is a great feat for Lekma Hospital, and we are very excited to see that our efforts at fighting AMR have been recognized. This prize will be used to finance more campaigns against AMR and equip our microbiology laboratory.

Dr. Akua Gyimah-Asante, Medical Superintendent at Lekma Hospital



**STEWARDSHIP
PRIZE WINNER**

Clinical Engagement Program, Pakistan

The Clinical Engagement Program is a program that provides capacity-building support for clinics and hospitals across the country. Led by the Indus Hospital and Health Network, the program aims to engage clinicians and microbiology staff to better manage the crisis posed by AMR.

Since 2021, the Clinical Engagement Program has worked to:

- Raise awareness of the challenges posed by AMR in Pakistan.
- Organize trainings for clinicians on proper antibiotic use.
- Conduct supervisory checks of antibiotic prescriptions in clinics and hospitals.



We are very privileged to have been awarded the AMR Industry Alliance Stewardship Prize. DAI has been working with public sector hospitals across Pakistan to initiate the 'AMR Stewardship' signature framework. We have seen an increase in laboratory testing for patients, before doctors diagnose and prescribe antibiotics, across these facilities. We're honored that the Alliance is rewarding our program as a best practice in responsible antimicrobial access through coordinated, proven, and implementable stewardship practices and protocols. We have planned to use the prize money to further support the technical capacities of the healthcare providers in strengthening 'AMR Stewardship' in selected public sector hospitals across Pakistan.

Dr. Qadeer Ahasan, Acting Team Lead, DAI Fleming Fund Country Grant, Pakistan



Manufacturing

Setting the standard
for mitigating
the environmental
effects of AMR



2022 ALLIANCE MANUFACTURING ACTIONS:

Default Predicted No-Effect Concentrations Guidelines

Antibiotic Manufacturing Standard

AMR Industry Alliance Commitments in Manufacturing

Review Alliance members' own manufacturing and supply chains to assess good practices in controlling the release of antibiotics into the environment.

Establish a common framework for managing antibiotic discharge and start applying it across their own manufacturing and supply chains by 2018; continue to implement the framework in the following years to reduce environmental risk due to manufacturing discharges.

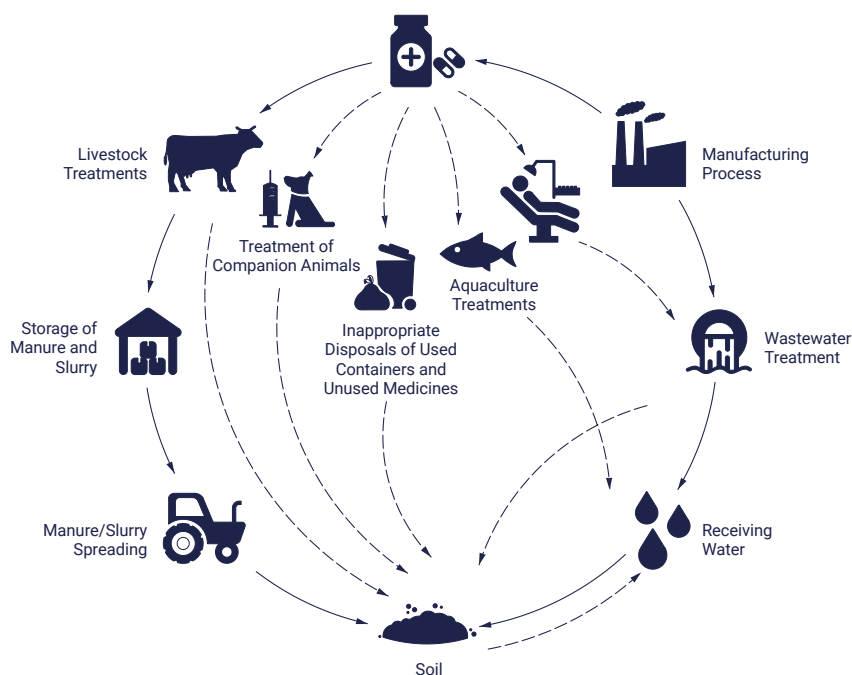
Work with stakeholders to develop a practical mechanism to transparently show that Alliance members' supply chains meet the framework's standards.

Work with independent technical experts to establish science-driven, risk-based targets for discharge concentrations of antibiotics, develop good-practice methods to reduce environmental impacts of manufacturing discharges by 2020 and work with Alliance members to ensure that discharge targets are met.

Manufacturing discharge of active pharmaceutical ingredients are typically not regulated globally – this is where the Alliance is playing a key role in filling a gap. While the major source of pharmaceuticals in the environment is believed to result from patient use of medicine and subsequent excretion, emissions of antibiotics in wastewater streams may contribute to the development of AMR unless concentrations in receiving waters are below levels likely to create selective pressure on bacteria to mutate. To address this issue, all manufacturing members of the Alliance have committed to strive to meet the requirements of the *Antibiotic Manufacturing Standard* including the Default Predicted No-Effect Concentrations as a condition of membership in the Alliance.

Since its inception in 2017, the AMR Industry Alliance has consistently played a leading role in creating and adhering to responsible manufacturing practices for antibiotics.

SOURCES OF ANTIMICROBIALS IN THE ENVIRONMENT



SOURCE: *Antibiotic manufacturing standard, Minimizing risk of developing antibiotic resistance and aquatic ecotoxicity in the environment resulting from the manufacturing of human antibiotics*, June 2022

Default Predicted No-Effect Concentrations Guidelines

The AMR Industry Alliance Common Antibiotic Manufacturing Framework and associated Predicted no-effect concentrations (PNECs) were published in 2018. **The Alliance reviews new toxicity test data generated by industry and available through literature to update PNECs for antibiotic production annually.** In 2022, the Alliance established a default PNEC which may be used in manufacturing emission risk

assessments of an antibiotic without a substance specific PNEC. The rationale for establishing the default PNEC was published in the peer reviewed scientific publication, *Integrated Environmental Assessment and Management*. Current Alliance PNECs and associated **supplemental information** is published on the Alliance web site.

AMR INDUSTRY ALLIANCE (PNECS) RESEARCH & RECOMMENDATIONS

Integrated Environmental Assessment and Management, Volume 18, Issue 4, published with supplementary materials:

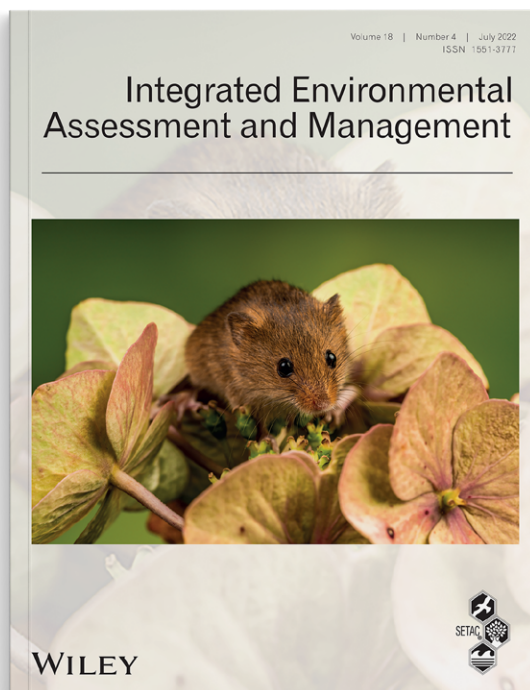
Making antibiotics responsibly

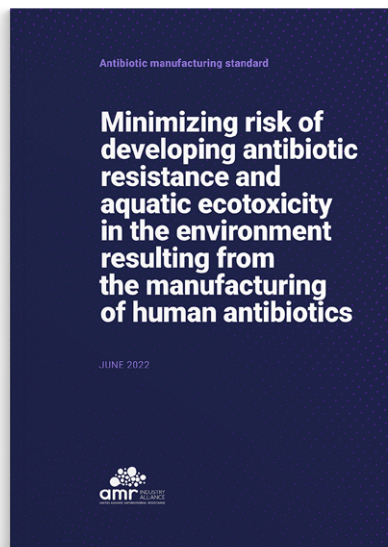
On-Going Supplementary Table

AMR Alliance Science-Based PNEC

Targets for Risk Assessments

Common Antibiotic Manufacturing Framework





Antibiotic Manufacturing Standard

In June 2022, the AMR Industry Alliance launched the *Antibiotic Manufacturing Standard*, developed through facilitation by the British Standards Institution (BSI). The Standard provides clear guidance to manufacturers in the global supply chain to ensure antibiotics are made responsibly, reducing concentrations of antibiotics in the environment minimizing the potential for development of AMR. It formalizes the Common Antibiotic Manufacturing Framework established in 2018.

The Standard requires:

- An environmental management system and risk-based approach to assessing and controlling antibiotic manufacturing waste streams.
- Adherence to published Predicted No-Effect Concentrations (PNEC), concentrations unlikely to result in increased risk of resistance.

An independent, third-party certification program to validate antibiotic product conformance to the *Antibiotic Manufacturing Standard* is in development and will be introduced by BSI in 2023.

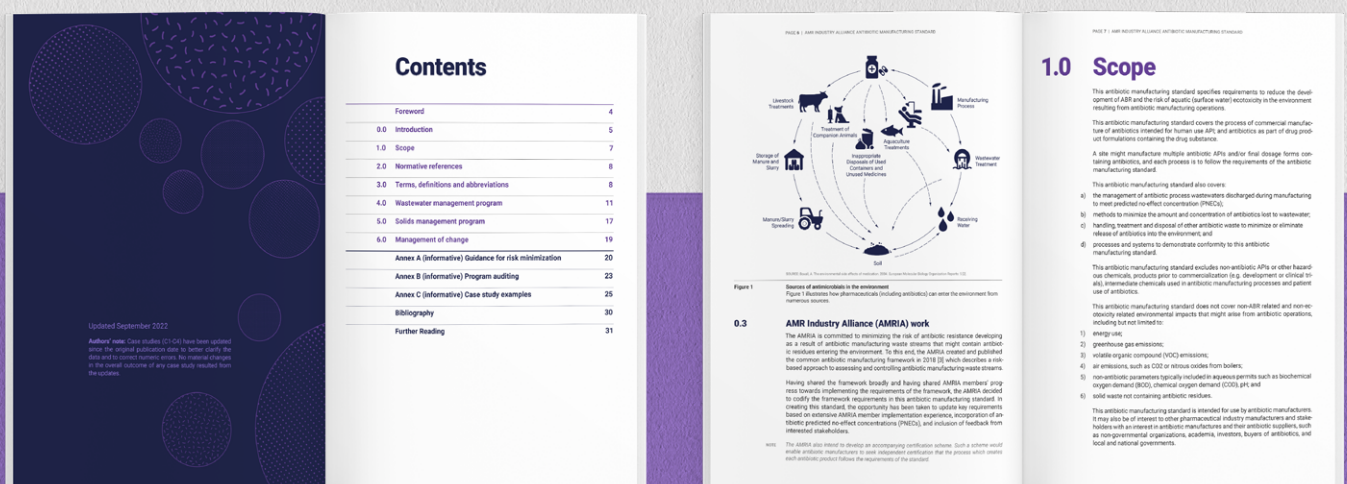
The Standard has received global attention and recognition, including coverage in *Reuters* and *European Pharmaceutical Review*, and has been spotlighted across global, regional and national forums.



The AMR Industry Alliance has taken a bold step towards combatting the spread of AMR in the environment. The...standard...will build much needed global awareness, encourage decisive actions, and provide an external, independent assurance mechanism....

Courtney Soulsby, Global Director of Healthcare and Life Sciences, BSI

ANTIBIOTIC MANUFACTURING STANDARD



“

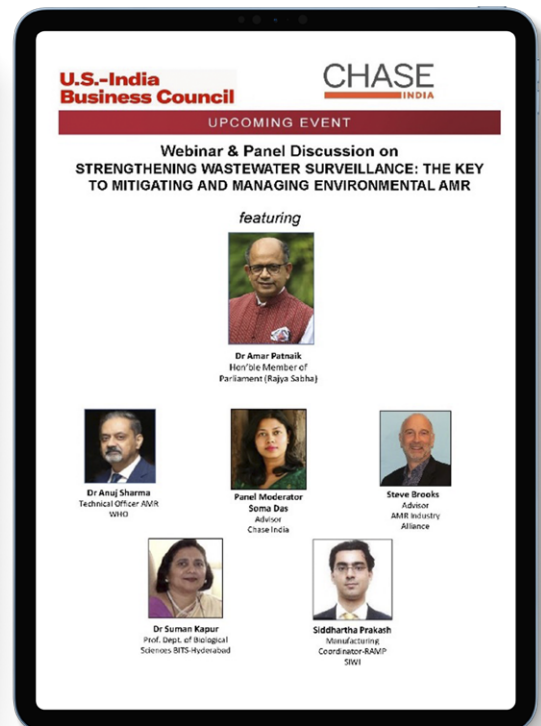
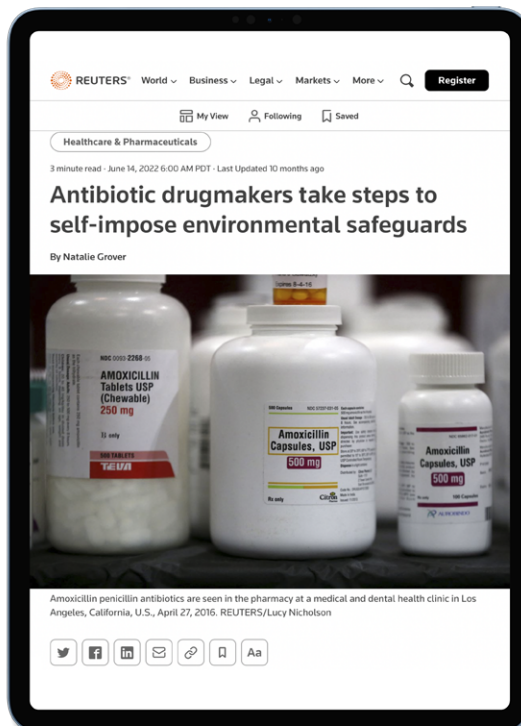
In the absence of global standards limiting toxic emissions produced by antibiotics at the point of manufacture, the pharmaceutical industry has come up with its own standard.

“Antibiotic drugmakers take steps to self-impose environmental safeguards”

by Natalie Grover, Reuters

In July 2022, the AMR Industry Alliance participated in a webinar, *Strengthening Wastewater Surveillance: The Key to Mitigating and Managing Environmental AMR*, held jointly by US-India Business Council (USIBC) and Chase India. Monitoring and addressing AMR in wastewater is a critical factor in combatting AMR which requires a multi-sectoral approach across public and private entities. Adequate sanitation and wastewater management is a major part of managing the level of AMR in the environment, but waste discharge from manufacturing facilities is an opportunity for industry to lead by example in addressing AMR. The webinar highlighted the Manufacturing Standard as a roadmap for implementing responsible manufacturing processes.

Following the webinar, *The Economic Times of India* published an **opinion piece** promoting the Standard for industry self-regulation to supplement India's National Action Plan on AMR in the absence of legal limits. The author of this article, Manufacturing Working Group Chair Steve Brooks, also advocates for a more robust national monitoring framework, for which the Manufacturing Standard and the proposed certification scheme could serve as model. Given India's importance to the fight against AMR as the world's largest producer of generic pharmaceuticals, the AMR Industry Alliance will continue to advocate and partner to advance solutions to reduce antibiotic manufacturing emissions in India.



In a first for the World AMR Congress, the topic of the environment was featured on the main platform in September 2022. In a panel discussion brought together by the AMR Industry Alliance and member company Centrient, leaders discussed the importance of the environment in the development and spread of AMR, and tactics to mitigate AMR risk. Panelists from the Alliance and Centrient, along with the Wellcome Trust and the Access to Medicine Foundation, discussed the need to dedicate attention to the many environmental sources that may be contributing to development and spread of AMR. The conversation highlighted the Alliance's Standard as an important action for antibiotic manufacturers to help them play their part in addressing the AMR risk.



Responsible manufacturing is an area where the companies have made progress on setting discharge limits, though more work remains on compliance. We also need to bring suppliers into the fold.

Marijn Verhoef, Director of Operations and Research, Access to Medicine Foundation

As the largest industry group dedicated to addressing AMR, we encourage all antibiotic manufacturers to take action. The problem will not be solved until the vast majority of antibiotics are made responsibly.

Steve Brooks,
Advisor, AMR Industry Alliance



Research & Science

Addressing barriers
to innovation



2022 ALLIANCE RESEARCH & SCIENCE ACTIONS:

Report: Drug Regulatory Approvals and Opportunities for Antimicrobial Innovation – Perspectives from Brazil, India and South Africa

AMR Industry Alliance Commitments in Research and Science

Invest in research and development for innovative antibiotics and dosage forms, vaccines, new technologies, and diagnostics.

Continue to advocate for policies that support sustainable investment in AMR-relevant innovation.

Partner with policymakers, payers and other relevant stakeholders on new reimbursement, valuation and commercial models that support appropriate patient access and a sustainable supply of antibiotics, AMR-relevant vaccines, new technologies and diagnostics.

Support collaboration and sharing of relevant non-proprietary data with different stakeholders (e.g. academia, consortia, SMEs, public researchers and industry) to help address key scientific and public health challenges.

Antimicrobial research and development is stagnating.

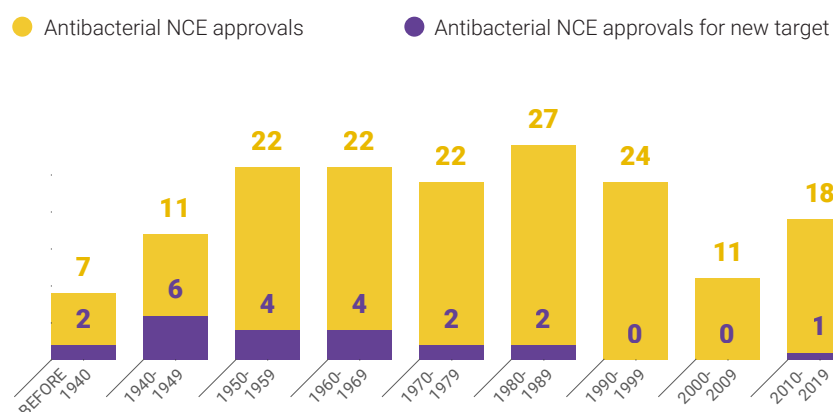
Approvals of novel drugs have slowed dramatically. In the 50 years, from 1950 to 2000, the US FDA approved an average of 23 new antimicrobials per decade. Since 2000, the number of average approvals per decade has fallen to 14. Furthermore, of 53 antibiotics approved by FDA over the last 3 decades, only one has been a direct-acting new drug against a new target.⁶

Antimicrobial and diagnostic innovation is crucial to the fight against AMR.

Although many AMR Industry Alliance members continue to fund new R&D, with members currently investing US\$1.8 billion–1.9 billion per year, market conditions can make it difficult to succeed with new projects.⁷

Under its four commitments on research and science, the AMR Industry Alliance is working to identify the causes of market issues and promote effective solutions. Thus far, the Alliance has advocated for policies needed to promote further R&D, supported collaboration and the sharing of non-proprietary data, and produced original research considering the state of current regulatory systems and proposing select improvements.

TIMELINE OF FSA APPROVED DIRECT-ACTING ANTIBACTERIAL NEW CHEMICAL ENTITIES (NCES) 1900-2019



SOURCE: <https://www.bio.org/sites/default/files/2022-04/BIO-Antibacterial-Report-2022.pdf>

Report: Drug Regulatory Approvals and Opportunities for Antimicrobial Innovation – Perspectives from Brazil, India and South Africa

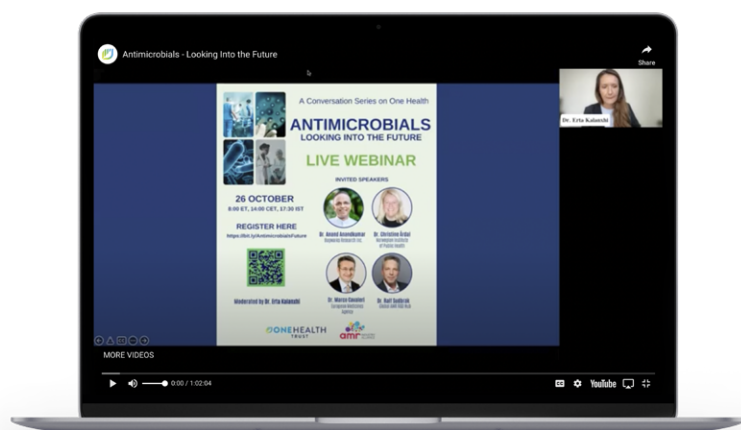
The AMR Industry Alliance, in partnership with One Health Trust, released the report *Drug Regulatory Approvals and Opportunities for Antimicrobial Innovation – Perspectives from Brazil, India and South Africa* in July 2022. The report highlights the importance of explicitly recognizing new anti-

microbials targeting serious or life-threatening infections as a critical unmet medical need. The report analyzes the regulatory framework for antibiotic approval in three middle-income countries, South Africa, Brazil, and India, and offers the following recommendations:

REGULATORY FRAMEWORK FOR ANTIBIOTIC APPROVAL RECOMMENDATIONS

- 1 Create a specific category for antimicrobials that target serious and life-threatening infections within the regulatory framework provided for accelerated approval pathways.
- 2 Leverage existing programs for expedited approval for drugs targeting TB, HIV, and COVID-19 to accelerate the approval of antimicrobials targeting serious and life-threatening infections, such as multidrug-resistant infections.
- 3 Increase regulatory authorities' capacities to deal with the complexity of AMR and novel clinical trials.
- 4 Increase regulatory harmonization to facilitate the adoption of reliance pathways for accelerated approval of antimicrobials.





Antimicrobials – Looking into the Future is part of One Health Trust *Conversation Series on One Health*. In this webinar, the AMR Industry Alliance in partnership with One Health Trust gathered a group of experts to share their insights into the future of antimicrobial development and access.

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The report concluded that significant regulatory system strengthening is needed through the implementation of technology-driven solutions, increased staffing for increased capacity, and the adoption of agency approvals. Increased internal coordination, decreased reliance on external assessors and early application support would lead to more timely evaluation of applications. One Health Trust also found the extension of the adoption of risk-based approaches to antimicrobials specifically critical to expediting

access to new antimicrobials. The report recommended the utilization of the momentum generated by the immediacy of Covid-19 to improve national and international collaborations and fast-track processes.

Following the release of the report, the AMR Industry Alliance and One Health Trust held the webinar *Antimicrobials – Looking Into the Future*, with speakers Dr. Anand Anandkumar (Bugworks Research Inc.), Dr. Christine Årdal (Norwegian Institute of Public Health), Dr. Ralf Sudbrak (Global AMR R&D Hub), Dr. Marco Cavaleri (European Medicines Agency), moderated by Dr. Erta Kalanxhi (One Health Trust). These experts discussed the future of antimicrobial development and access, such as the implications of the current need for new antimicrobials, how the significant challenges associated with their development and access need to be addressed, and what needs to be done to ensure better access in the future.



There is a lot of good news, but the entire system is very fragile... [but] even if the companies are bringing drugs to the market, the majority of companies go bankrupt even after they have successfully launched a new antibiotic in the market.

Dr. Ralf Sudbrak, Interim Secretariat Co-Lead, AMR R&D Hub

We need to find a streamlined regulatory process of new antibiotics or new molecules that could tackle the issue of AMR, but we need evidence that the products will be effective and safe... It might be a good starting point to try to build consensus or try to get an alignment with the requirements that will not be only for those agencies in high-income countries but spread across the globe so that we are all looking at the data in the same way, looking into the requirements in a more consistent way.

Dr. Marco Cavaleri, Head of Biological Threats and Vaccines, European Medicines Agency



LOOKING
FORWARD

Looking Forward

The members of the AMR Industry Alliance recognize and take seriously the important role of private-sector leaders in tackling AMR – as innovators, as employers, and as responsible global citizens. Through the Alliance, industry leaders from biotech, diagnostics, generics and R&D pharma companies come together and partner with other global leaders to tackle the challenges to access to antibiotics; adopt and replicate best practice in appropriate use and stewardship; set an example for mitigating environmental impacts; and support ongoing research and innovation. Through its reports, initiatives and engagement in the global dialogue on AMR, the Alliance strives to be a valued partner and changemaker.



In 2023, the Alliance will build upon our work and progress in 2022. It will continue its practice of surveying members about action, progress and outlook toward curbing AMR. Through a company self-reported survey conducted by RAND Europe, these results will provide a glimpse into the future of R&D investments and progress on responsible manufacturing. The AMR Industry Alliance intends to share key outcomes and data during World Antimicrobial Awareness Week in November.

Stewardship Prize

In addition, the annual Stewardship Prize will continue to be a hallmark of the Alliance's work, engaging externally and showcasing best practice in locations where stewardship is most critical.

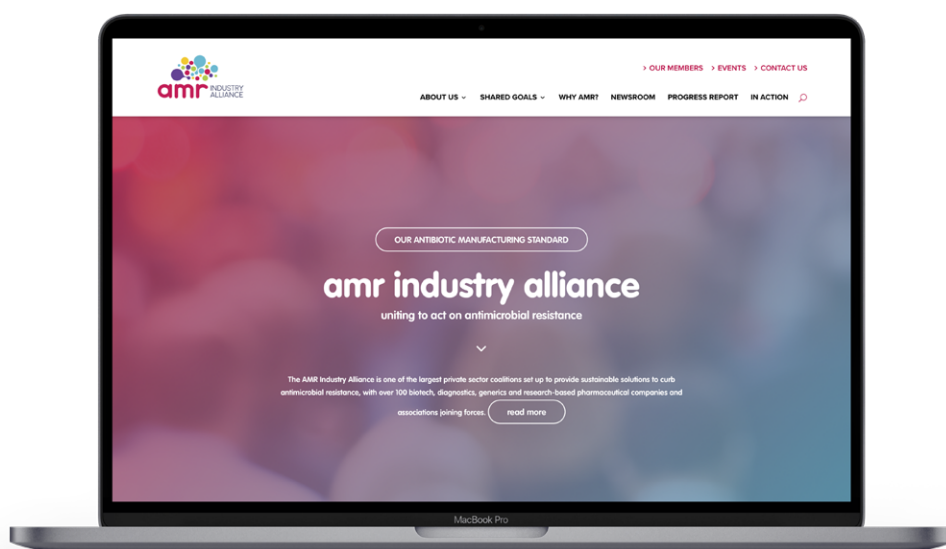


Finally, BSI will be launching the manufacturing certification scheme in mid-2023, building on the Alliance's Standard. Certification will be open to Alliance members and non-members alike to encourage broader compliance with responsible manufacturing processes across the industry. The Alliance will encourage certification and will continue working toward the widespread adoption of the Standard across all antibiotic manufacturers and in procurement tendering processes. The magnitude of impact that these actions can have in the reduction of environmental AMR risk still remains to be seen, but starting now will go a long way towards global, systemic change.



In planning for 2023 to 2025 and beyond, the Alliance is committed to further engaging stakeholders in geographic areas currently underrepresented by its membership. The Alliance will join with global stakeholders to promote an international focus on AMR, actively engaging with likeminded external stakeholders such as WHO, GARDP, and the Wellcome Trust, bringing our unique private-sector voice to global gatherings where the change is being made.

As we continue our important advocacy and research work toward building awareness and providing solutions, we invite continued collaboration with governments, multi-lateral organizations, non-governmental organizations, academic institutions and patient advocacy groups to help us bring about progress in the critical fight against AMR.





Endnotes

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ABOUT THE AMR INDUSTRY ALLIANCE

The AMR Industry Alliance is a coalition of over 100 biotechnology, diagnostic, generics and research-based biopharmaceutical companies and trade associations that was formed to drive and measure industry progress to curb antimicrobial resistance. The AMR Industry Alliance will ensure that signatories collectively deliver on the specific commitments made in the Industry Declaration on AMR and the Roadmap and will measure progress made in the fight against antimicrobial resistance.

amrindustryalliance.org

IFPMA serves as the Secretariat for the AMR Industry Alliance.
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