



# Access

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

### AMR Industry Alliance Commitments in Access

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

Work in collaboration with policy-makers 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.** The AMR Industry Alliance has made commitments to improving access to antimicrobials and diagnostics across the world. 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.

### 2022 ALLIANCE ACCESS ACTIONS:

#### Access Framework for LMIC Hospitals

In 2022, the Alliance developed an access framework intended to determine the feasibility of targeted pilots to further access in LMICs in partnership with Mann Global Health. The framework provides insight on action items for hospitals and enables collaboration and information gathering from external stakeholders.

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

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. 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. The **final report** was published in early 2023.

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

The Alliance further highlighted the importance of strengthening the sustainability of the antimicrobial supply chain in a webinar organized during World Antimicrobial Awareness Week (WAAW), **Multi-Sectoral Approaches to Responsible Access: Working Together to Fight AMR**.





# Appropriate Use

## Promoting awareness and stewardship in the use of antibiotics

### 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.

**The inappropriate use of antibiotics is a serious problem that threatens lives, contributes to lengthened recovery times, and exacerbates the spread of AMR.** The AMR Industry Alliance is working to build awareness about this issue, bolster surveillance systems, and develop new diagnostic tools to help ensure better antimicrobial stewardship.

### 2022 ALLIANCE APPROPRIATE USE ACTIONS:

#### 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. In 2022, the Alliance selected Lekma Hospital in Ghana and the Clinical Engagement Program in Pakistan as the winners of this prize. Lekma Hospital established an AMR surveillance project focused on laboratory and pharmacy surveillance, an awareness campaign, and training for staff and community pharmacists. The Clinical Engagement Program is a program that provides capacity-building support for clinics and hospitals across Pakistan.

#### Value of Diagnostics Survey and Report

The 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.

#### 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 resistant infectious diseases. The TBC-Alliance program will roll out in fall 2023.





# Manufacturing

## Setting the standard for mitigating the environmental effects of AMR

### 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.** 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.

### 2022 ALLIANCE MANUFACTURING ACTIONS:

#### 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*.

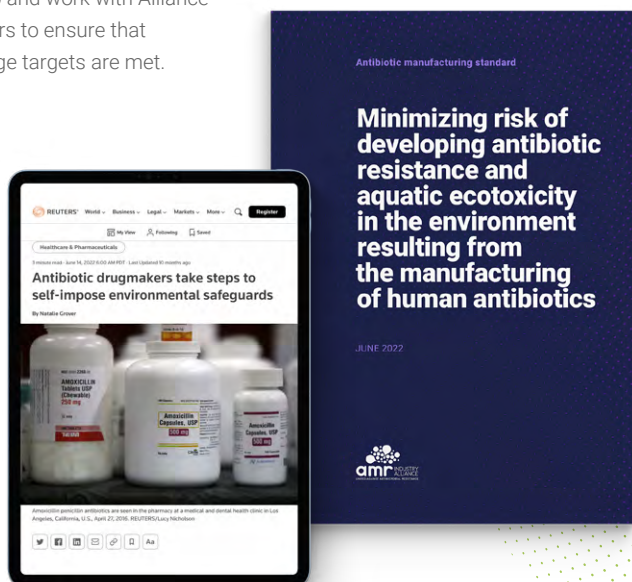
#### Antibiotic Manufacturing Standard

In June 2022, the AMR Industry Alliance launched the *Antibiotic Manufacturing Standard*, developed through facilitation by the British Standards Institution (BSI).

The Standard 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), safe 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.





# Research & Science

## Addressing barriers to innovation

### AMR Industry Alliance Commitments in Research & 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 has slowed dramatically.** Although AMR Industry Alliance members continue to fund new R&D with US\$1.8 billion–1.9 billion per year, market conditions can make it difficult to succeed with new projects. 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.

### 2022 ALLIANCE RESEARCH & SCIENCE ACTIONS:

#### 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 antimicrobials targeting serious or life-threatening infections as a critical unmet medical need.

It 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.

#### Webinar: *Antimicrobials – Looking Into the Future*

AMR Industry Alliance and One Health Trust organized a webinar to draw attention to the significant challenges associated with antimicrobial development and access and discuss what needs to be done to solve those challenges in the future.

