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

ABOUT SUSTAINABILITY

SustainAbility is a consultancy and think tank enabling business to lead on the sustainability agenda.

sustainability.com

PUBLICATION DATE: JANUARY 2020
Every year at least 700,000 people die from drug-resistant infections, or antimicrobial resistance (AMR).\(^1\) If AMR remains unchecked, the annual death toll could climb to 10 million by 2050\(^2\) and the economic impacts could be on par with the 2008 financial crisis.\(^3\)

The rapid development and spread of AMR is a global public health crisis, undermining the many advances in medical treatment that are underpinned by the availability of safe and effective antimicrobials. Without effective antimicrobials, preventing and treating infectious diseases will become more challenging, and common medical treatments and simple surgeries such as cancer chemotherapy and caesarean sections will carry significantly higher risks for patients.\(^4\) AMR also poses challenges for the treatment of lung infections for people with cystic fibrosis\(^5\), and limits treatment options for those with kidney disease.\(^6\)

AMR is a global problem. Resistant bacteria, fungi, and other pathogens know no borders. The complex social, scientific, and economic issues driving AMR cannot be resolved without strong collaboration between the private and public sectors. Protecting patients and counteracting a public health crisis, which can potentially undermine entire health systems, requires a coordinated global response by all stakeholders, including governments, civil society, academia, international health agencies, health care providers, and the life sciences industry.

The AMR Industry Alliance (“the Alliance”) was established in 2017 to report on and drive progress on AMR by the life sciences industry. Representing a diverse coalition of biotechnology, diagnostics, generics, and large research-based biopharmaceutical companies and associations, Alliance members commit to action in four key areas: research & science, access, appropriate use, and manufacturing.

ALLIANCE COMMITMENTS

- RESEARCH & SCIENCE
- APPROPRIATE USE
- ACCESS
- MANUFACTURING & ENVIRONMENT
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.

APPROPRIATE USE

- Contribute to slowing the emergence of resistance by preventing infections by promoting vaccination and reduction of inappropriate use of antibiotics through expanded use of diagnostics.
- Support 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 are aligned with the goal of advancing stewardship.

MANUFACTURING & THE ENVIRONMENT

- Review Alliance members’ own manufacturing and supply chains to assess good practice in controlling releases of antibiotics into the environment.
- Establish a common framework for managing antibiotic discharge, and start to apply it across their own manufacturing and supply chains by 2018.
- Work with stakeholders to develop a practical mechanism to transparently show that Alliance member supply chains meet the framework’s standards.
- Work with independent technical experts to establish science-driven, risk-based targets for discharge concentrations of antibiotics and develop good practice methods to reduce environmental impacts of manufacturing discharges by 2020.

RESEARCH & SCIENCE

- Invest in research and development for innovative antibiotics and antibiotic 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 sustainable supply of antibiotics and AMR-relevant vaccines and new technologies and diagnostics.
- Support collaboration and sharing of relevant non-proprietary data with different stakeholders (e.g., academia, consortia, small or medium-sized enterprise (SMEs), public researchers, and industry) to help address key scientific and public health challenges.
ABOUT THIS REPORT

Similar to the Alliance’s first biennial report, the second report is based on a comprehensive member survey that tracks progress in fulfilling commitments made by Alliance members. The survey forms the basis of Alliance progress reports. The first report was published in January 2018 based on results of a survey conducted in 2017, in which 37 out of 101 eligible members participated. The response rate nearly doubled in 2019, with 65 out of 91 eligible members responding to the Alliance survey, resulting in a response rate of 71.4%. The purpose of the survey conducted in 2019 among all member companies of the Alliance representing the four life sciences subsectors—large research-based biopharmaceutical, generics, diagnostics, and biotechnology companies—was to collect information on the activities of Alliance members and offer a unique insight into the status of actions taken by those leading organizations in the life science industry who elected to join the Alliance and play their part in addressing AMR. By highlighting best practice, the Alliance seeks to drive progress on AMR across the life sciences industry.

Taken together, the Alliance likely represents approximately one third of the global antibiotic supply* and nearly half of AMR-relevant products in clinical development. With a higher survey response rate, the report provides a detailed snapshot of member companies’ collective efforts, highlighting best practice examples from the industry and identifying opportunities for companies and other stakeholders to drive further progress in the fight against AMR.

The report contributes to the global response to the AMR challenge by documenting Alliance members’ activities in the areas of research & science, access, appropriate use, and manufacturing. It not only offers consolidated data on member companies’ AMR-related actions and partnerships, but it also gives an account of a variety of antimicrobial products and diagnostic tools that are already available on the market or in development. The report includes a number of case studies from all four sectors of the life sciences industry. The case studies present efforts by individual member companies and demonstrate their strong commitment to investing in AMR-related research & science; improving access to and optimizing use of antimicrobials, vaccines, and diagnostics tools; and promoting the responsible manufacture of antibiotics.

* Calculation based on 2018 sales data from IMS Padds. The data are based on sales in 67 countries, excluding India; they cover 300 molecules and concern antibiotics for human use only.
The report provides a unique snapshot of the life sciences industry’s collective efforts and leadership in delivering on their commitments to tackle the rise of AMR.

The Research & Science chapter shows that the level of R&D investment in clinical development is likely insufficient to meet global health needs. This contrasts with a more vibrant and robust biotechnology preclinical pipeline and new rapid infection detection tests that are being developed by diagnostics companies. This mismatch means that many of these early-stage compounds may never reach patients unless new mechanisms and incentives are put in place to improve current market conditions and support the development and commercialization of novel solutions to tackle AMR. Of the companies surveyed for the Alliance report, 74% are likely to increase investments in AMR if the commercial environment improves.

The Access chapter highlights how Alliance companies are acting on commitments to improve patient access to appropriate, high-quality antibiotics as well as vaccines and diagnostics that can help prevent, detect, and treat drug-resistant infections.

Results in the Appropriate Use chapter showcase how Alliance members are supporting stewardship. All companies reported that they are investing in a wide range of measures to promote appropriate use of antibiotics in order to slow the emergence of resistance, prolong the effectiveness of antimicrobials, and improve health outcomes for patients.

The Manufacturing Environmental chapter reports that Alliance members, which own a total of 208 antibiotic manufacturing sites, are two years ahead of schedule in establishing an industry standard for reducing the potential environmental risks from antibiotic production, including emissions that may contribute to the emergence of resistant bacteria. The Alliance has set out a common framework for responsible antibiotic manufacturing to reduce the environmental impact of production. So far, the findings show that more than 80% of participating companies have assessed
all their antibiotic manufacturing sites against this new industry standard and 82% meet or partially meet the framework’s requirements. Manufacturing members also conveyed the framework requirements to just more than half of the 900 plus suppliers they use.

Looking to the future, the report makes recommendations on how Alliance members and the broader life sciences industry can contribute further to the global response to AMR. This includes accelerating the sharing of data to promote innovation and making surveillance data publicly available, including data on infection rates, AMR patterns, and antibiotic use. Partnerships already feature strongly in many areas of Alliance company activities. The report proposes areas where new or deeper partnerships with governments, patients, and providers are required, such as improving market conditions necessary for sustainable development and commercialization of novel solutions to AMR, and strengthening local healthcare and laboratory capabilities to support effective diagnosis and treatment of drug-resistant infections.

Below is the overview of key findings in each of the Alliance's four areas of work.

**RESEARCH & SCIENCE**

**RESEARCH & SCIENCE HIGHLIGHTS**

**INDUSTRY REMAINS THE DOMINANT FUNDER OF AMR-RELEVANT R&D:** Overall, in 2018 Alliance members invested more than US$1.6B into the development of AMR-relevant products to combat AMR. These include antibiotics, antifungals, and novel technologies; vaccines; and diagnostic platforms and assays. Alliance member companies are developing ~50% of the Pew Charitable Trusts’ lists of ‘Antibiotics Currently in Global Clinical Development’ and ‘Nontraditional Products for Bacterial Infections in Clinical Development’.

**INVESTMENT LEVELS ARE THREATENED:** The overall economic environment remains challenging for novel antibiotics, and the investment figure reflects several exits both by large research-based biopharmaceutical companies and biotechnology companies since the previous report. Despite important investment from diagnostics companies, the overall Alliance investment figure is lower than that reported in the previous report. Alliance members reported that this decline in AMR-relevant investment is likely to continue unless governments take action to improve antibiotic reimbursement and implement new incentives.

**ALLIANCE COMPANIES ARE ENGAGED IN MULTI-STAKEHOLDER EFFORTS TO FIND SOLUTIONS:** Ninety percent of relevant companies engage in national and international partnerships to combat AMR. This includes engaging in public–private partnerships such as CARB-X, the Human Vaccine Project, and Innovative Medicines Initiative's COMBACTE partnership, as well as working directly with non-governmental organizations (NGOs), academia, government departments, international agencies such as the World Health Organization, and hospital and medical laboratories, to advance solutions on AMR.

---

* Companies from the large research-based biopharmaceutical, biotechnology, and diagnostics sectors were asked to respond to some or all of the survey in relation to Research & Science.

† Pew is an independent, non-partisan, non-profit organization dedicated to serving the public across a number of focus areas. Within its work in health, Pew has developed the Antibiotic Resistance Project, which addresses key AMR issues.
ADVANCING PRODUCTS THAT COMBAT AMR

Alliance member R&D investments are focused on the microorganisms that pose the greatest threats to human health, including those listed on the World Health Organization (WHO) Priority Pathogen List\(^9\) and the “biggest threats” identified by the U.S. Centers for Disease Control and Prevention (CDC).\(^{10}\) In response to these globally agreed priority areas, Alliance members continue to build the R&D pipeline to combat AMR, which includes antibiotics, antifungals, vaccines, novel approaches or technologies, diagnostic platforms and assays, and other AMR-relevant products. There are encouraging compounds in Alliance member company pipelines, particularly from biotechnology companies, and many new rapid infection detection tests are being developed by diagnostics companies. Alliance members are developing ~50% of the Pew Charitable Trusts’ lists of ‘Antibiotics Currently in Global Clinical Development’\(^{11}\) and ‘Nontraditional Products for Bacterial Infections in Clinical Development’\(^{12}\).

Overall, in 2018 a total of 56 Alliance members invested more than US1.6B into the development of AMR-relevant products to tackle AMR, including 24 antibiotics and antifungals, 11 vaccines, 16 diagnostic platforms or assays, 10 non-traditional approaches, and 1 other AMR-relevant product. This is a subset of the overall Alliance and private-sector investment in AMR-relevant R&D. Since the public sector invests approximately US500M per year in AMR-relevant R&D,\(^{13}\) this report shows that the life sciences industry remains by far the dominant funder of AMR-relevant R&D.

However, these investment levels are threatened. The overall economic environment remains challenging for novel antimicrobials and the investment figure reflects several exits of large research-based biopharmaceutical companies (e.g., Novartis, Sanofi, and AstraZeneca) and biotechnology companies (e.g. Achaogen’s bankruptcy), which occurred since the previous progress report was published in January 2018. Despite important increases in investment by diagnostics companies, the overall investment figure is likely not sufficient to deliver the tools needed to address AMR. Investment levels may further decrease in the coming years if governments do not take urgent action to improve antibiotic reimbursement systems and implement new incentives for development.

These potential changes to investment levels were flagged in the previous Alliance report, where 30% of Alliance companies active in antimicrobial R&D said they would likely decrease investment in this area if no new incentives were established and commercial models remained the same.\(^{14}\) Since that report, no country has made fundamental changes to the way that antimicrobials are valued and reimbursed, or implemented any new pull incentive.\(^{15}\) While some novel reimbursement approaches have been proposed, notably in Sweden, the U.K. and U.S., they have not yet been implemented. Until a package of incentives, including reimbursement reform and novel pull incentives to address the well-documented economic challenges in the antibiotic market, are introduced, private investment into antibiotic development is likely to continue to decline.

Despite the lack of progress with pull incentives, according to the survey results, 74% of companies are likely to increase investments in AMR-relevant R&D if the commercial environment improves. To unlock greater investment and successfully bring more products in the pipeline all the way to patients who need them, Alliance members continue to advocate and partner with governments in the development of new reimbursement models and pull incentives that would strengthen the commercial viability of antimicrobial R&D.
ADVANCING DIAGNOSTICS R&D

Advancing the diagnostics pipeline is a crucial element of industry solutions and responses to AMR, helping to improve patient health in countries all around the world. Alliance diagnostics members are actively pushing this agenda, significantly increasing the resources they dedicated to this urgent issue over the past 2 years. Across the Alliance, 15 diagnostic platforms or assays are in the clinical pipeline. Seventy percent of Alliance diagnostics members are active in clinical and early stage R&D, developing reagents, hardware, software, and middleware. These solutions provide significant economic and medical value, giving healthcare providers easy-to-use systems that provide fast, accurate information and access to data analytics that can support clinical decision making and follow-up of the epidemiology.

ACCESS

ACCESS HIGHLIGHTS*

An estimated 5.7 million people a year die from treatable bacterial infections: The majority of these deaths occur in low- and middle-income countries (LMICs), where access to appropriate antimicrobials remains a significant health challenge.16 Alliance companies are acting on commitments to improve patient access to appropriate, high-quality treatments, vaccines, and diagnostics, while at the same time upholding appropriate use principles.

81% of respondents reported having developed comprehensive strategies to improve access
63% of respondents partner with governments, NGOs, industry trade groups, local healthcare institutions, and others to expand patient access to their AMR-relevant products
47% of responding companies reported experiencing product supply chain disruptions, despite ongoing efforts to build supply chain resilience.

EXPANDING ACCESS

AMR is a growing global threat. The unmet need for AMR is significant but enhancing access to antimicrobials in low- and middle-income countries remains challenging. Lower income countries with high burdens of infectious diseases and weak health systems often struggle to provide even basic access to generic antibiotics. There are additional challenges to enhancing appropriate access to novel antimicrobials designed to overcome emerging drug resistance.17 Enhanced access to antimicrobials (aligned with antimicrobial stewardship) can address this unmet medical need and slow the spread of AMR.

While there is global attention on the importance of expanding access to antimicrobials, there is no consensus yet on how to expand appropriate access to antibiotics in LMICs with weak health systems. More people die globally from lack of access to antibiotics than AMR,18 but how can we

* Companies from all sectors were asked to respond to some or all of the survey in relation to Access.
improve access to antimicrobials for those in need while curbing inappropriate and excessive use? The Alliance supported a study by the Center for Disease Dynamics, Economics & Policy (CDEPP) to unpick these complex challenges and identify ways to progress. Efforts are needed by many stakeholders to strengthen health systems and expand universal health coverage.

Eighty percent of Alliance member access strategies cover low-income countries. All large research-based biopharmaceutical and generics companies with commercialized products on the market have formalized access strategies in place, compared with 78% of diagnostics companies. A total of 43% of biotechnology companies with commercialized products on the market reported having access strategies in place, which is not surprising given the focus and nature of their businesses.

Strategies include expanding product registration, tiered pricing, compassionate use programs, and product donations. Specifically, members’ access plans cover: registration (84%), affordability (72%), partnerships (60%), and efforts to boost health systems’ capacity and appropriate use (60%). Just 32% of reporting companies publish their access strategies, a key area for improvement.

ENSURING CONTINUOUS SUPPLY OF ANTIMICROBIALS

Forty-seven percent of respondents reported disruptions in their supply chain of AMR-relevant products during the reporting period, down from nearly two thirds in the previous report. All generics and large research-based biopharmaceutical companies reported working closely with vendors and relevant authorities to address supply chain challenges. Activities reported to be underway to address supply chain challenges included diversifying supplier bases, continuing to implement robust quality systems and controls, building supplier capacity, and strengthening buffer stocks of vaccines and antimicrobials.

The safe supply of antimicrobials also requires curbing the black market in substandard and falsified medical products that endanger patients and contribute to spreading drug-resistant infections. The majority (88%) of large research-based biopharmaceuticals and all generics companies reported taking pre-emptive measures, including tamper-proof packaging, product serialization, and the establishment of counterfeit management teams. Members also work with the healthcare community, regulatory authorities, and law enforcement agencies to raise awareness of counterfeiting of diagnostic and biopharmaceutical products (i.e., vaccines and antimicrobial and antifungal drugs) and to work in partnership to monitor distribution channels.
PROMOTING SAFE USE OF ANTIMICROBIALS

Stewardship plans adopted by large research-based biopharmaceutical, generics, diagnostics, and biotechnology companies cover a wide range of activities targeting patients, physicians, and the public. The most common activities to promote appropriate use of antimicrobials by Alliance members focus on: education (80%), surveillance (73%), early and appropriate diagnosis (70%), generating evidence for appropriate use (60%), and promotion of appropriate use separately from promotion of products (50%). Reducing uncontrolled use (30%), supporting infection prevention and control (IPC) as well as water, sanitation, and hygiene (WASH) programs (30%) are activities that currently few Alliance members undertake. In the future, more members could work alongside governments and public health agencies to support them in the roll-out of IPC and WASH programs.

Stewardship aims to ensure that each patient receives the right drug for the right pathogen at the right time; prompt and accurate diagnosis of infection is an important component of these efforts. This means both knowing what pathogen is causing the infection (identification), how best to treat it (susceptibility), and how to do so in the fastest possible time. Diagnostic tools are crucial to ensuring that the use of antimicrobials can achieve the best patient and public health outcomes, including reducing the incidence of sepsis and reducing the inappropriate prescription of antimicrobials.

Increasingly, companies’ commercial promotional activity also takes into account AMR and the need for strong antimicrobial stewardship. Eighty percent of companies reported promoting products in ways that align with the goal of advancing stewardship. Examples of programs designed to promote appropriate use of antimicrobials include: placing messages on drug packaging to encourage patients to complete antimicrobial courses; distributing relevant materials in hospitals, schools, and at conferences; and developing non-branded materials that explain risks related to AMR. In addition, some companies work with international health organizations and NGOs to raise global public awareness of AMR and educate about the importance of using antimicrobials as prescribed.

* Companies from all sectors were asked to respond to some or all of the survey in relation to Appropriate Use.
While members and governments recognize the important role that vaccines can play in combatting AMR, this element continues to be under-prioritized for action. Progress towards achieving universal vaccination for high-burden diseases that contribute to AMR has been limited – for both bacterial and non-bacterial pathogens. Four companies that develop vaccines highlighted the role of prevention through vaccination programs in their appropriate use strategies. Members are continuing to invest in developing effective new AMR-relevant vaccines – including for several pathogens for which no vaccine is currently available, as a key step in the battle to contain drug resistance.

DETECTING RESISTANCE TRENDS

Surveillance of drug resistance is critical to the fight against AMR, supporting the appropriate use of antimicrobials and informing new products and platforms. Of relevant companies, 70% reported collecting such data on their products, and many are sharing these data with public health agencies, researchers, and prescribers.

Surveillance activities performed by generics, large research-based biopharmaceutical companies, and diagnostic companies range from local, hospital-level surveillance through monitoring of national and global trends. Diagnostic companies of the Alliance develop and deploy tools and technologies for early identification of resistant infections, which generate evidence that supports diagnostics’ clinical utility and promotes optimal use of antimicrobials.

MANUFACTURING

MANUFACTURING ENVIRONMENTAL HIGHLIGHTS*

Responsible manufacturing reduces potential environmental risks from antibiotic production, including emissions that may contribute to the emergence of resistant bacteria.

- **2** years ahead of schedule, the Alliance published predicted no-effect concentrations (PNECs), which can be used to establish discharge targets for antibiotic manufacturing site.
- **83%** of manufacturing company members have assessed all of their own antibiotics manufacturing sites against the Alliance’s new manufacturing framework.
- **82%** of owned sites meet the framework’s requirements wholly or in part.
- **56%** of products made at member-owned sites are expected to be made in accordance with discharge targets **within the next 3 years** and **88% within the next 7 years**.
- **24%** of products made at supplier sites are expected to be made in accordance with discharge targets **within 3 years** and a further **70%** of products made at supplier sites are expected to be made in accordance with these targets **within 4-7 years**.

* Companies from the large research-based biopharmaceutical and generics sectors, who have manufacturing operations, were asked to respond to the survey in relation to Manufacturing.
Recognizing the need to take action to reduce potential environmental risks from antibiotic production, including emissions that may contribute to the emergence of resistant bacteria, the Alliance’s Manufacturing Working Group is proactively leading on this issue.

Members not only established an industry standard for the environmental management of antibiotic manufacturing, but they did so two years ahead of schedule by developing unified, science-driven, risk-based targets, known as predicted no-effect concentrations (PNECs), to be used in the environmental assessments for factory discharges of antibiotics. Members have published an associated peer-reviewed paper, including the list of PNECs, for approximately 120 antibiotics. The Alliance expects that these PNECs will be used by all companies that manufacture antibiotics when establishing discharge targets for antibiotics in waste-water emissions from manufacturing plants.

Manufacturing members of the Alliance are committed to meeting these low discharge targets. To give some context, PNECs are typically established at the microgram/liter level (parts per billion). For a factory supplying one million antibiotic tablets per year, with the concentration of antibiotic in the collected waste water equalling the PNEC of 1 microgram per liter, collecting all the waste water produced during the year would not contain enough antibiotic to extract to make one tablet.*

The Alliance is increasingly recognized as an influential leader in this important area of AMR and, encouragingly, other organizations are adopting its framework. For example, Medicines for Europe, a trade association and an Alliance member, has committed to ensure that adherence to the Alliance's manufacturing framework and discharge targets is a condition of membership of all its association's generics company members (whether they are a member of the Alliance or not).

There are ongoing efforts to bring in new members to the Alliance and expand the adoption of recently established manufacturing standards. The Alliance has also supported a pilot project in India to encourage six local companies to adopt the framework and PNEC measures. Including non-Alliance companies in this work helps spread the awareness and uptake of these best practice standards.

**MAKING ANTIBIOTICS RESPONSIBLY**

The Common Antibiotic Manufacturing Framework ("the framework"), which was published in January 2018, provides companies with minimum site requirements to meet environmental standards and with an appropriate methodology to conduct risk assessments.

Alliance members reported a total of 208 antibiotic manufacturing-owned sites. As of June 2019, 92% of these sites have been assessed by members against the requirements of the framework, with 82% of assessed sites partially or fully meeting the requirements, and 18% not yet meeting them. Similarly, 32% of members’ supplier sites have been assessed by members against the requirements of the framework, with 33% of these supplier sites meeting the requirements, 37% partially meeting them, and 30% not meeting them. All Alliance manufacturing members reported making 624 antibiotic products at owned facilities, 88% of which are expected to be manufactured meeting the PNEC targets within the 7-year timeframe.

*Calculation basis: 100 tonne/yr API factory (equivalent to 200 million tablets) producing 100M3/day effluent at PNEC 1ug/l
Yields 0.35 tablets in effluent per 1 million tablets produced.
MAKING ANTIBIOTICS RESPONSIBLY

The Common Antibiotic Manufacturing Framework ("the framework"), which was published in January 2018, provides companies with minimum site requirements to meet environmental standards and with an appropriate methodology to conduct risk assessments.

Alliance members reported a total of 208 antibiotic manufacturing-owned sites. As of June 2019, 92% of these sites have been assessed by members against the requirements of the framework, with 82% of assessed sites partially or fully meeting the requirements, and 18% not yet meeting them. Similarly, 32% of members’ supplier sites have been assessed by members against the requirements of the framework, with 33% of these supplier sites meeting the requirements, 37%

NEXT STEPS

RESEARCH & SCIENCE

- In partnership with patients and providers, continue to advocate for governments to implement the package of policy reforms that would create market conditions that support sustainable investment into and commercialization of AMR-relevant R&D as well as diagnostics, vaccines, improvements to existing therapies, complementary technologies, and novel solutions. This could include piloting new payment mechanisms and pull incentives.
- Collaborate with international organizations, NGOs, research institutions, funders, and donors to accelerate development of new treatments for drug-resistant infections, particularly those prevalent in LMICs.
- Work with health systems and the broader pharmaceutical industry to ensure that vaccines, diagnostics, novel antibiotics, and other AMR-relevant products are appropriately valued.
- Strengthen partnerships on R&D within and outside the Alliance by making information available on companies’ various platforms publicly available to deepen the current understanding of resistance trends and resistance mechanisms and to promote innovation.
- Increase Alliance membership to cover a greater proportion of companies active in clinical R&D of AMR-relevant products.

ACCESS

- Encourage Alliance members to incorporate access to antimicrobials into R&D plans and increase transparency by making these access plans public.
- Increase Alliance membership to cover a greater proportion of the global supply of antimicrobials, with a particular focus on generic companies.
- Collaborate with local health authorities and policy makers to explore and support initiatives that will strengthen the long-term sustainability of the antimicrobial product market, improve supply chain security and continuity, and reduce drug shortages for AMR-relevant products. Initiatives could include improvements to contracting practices and incentives for investing in responsible manufacturing and continuity of supply.
Work in partnership with local governments and funding agencies to strengthen local healthcare and laboratory capabilities to support effective diagnosis and treatment of drug resistant infections.

Promote timely access to less expensive generic antibiotics through voluntary licensing agreements, particularly in lower- and middle-income countries, where there are systems in place to ensure appropriate use. Partner with funders and public health agencies to strengthen health system capacity.

Partner with governments and NGOs to strengthen and expand programs that clear regulatory burdens that may otherwise reduce broad global registrations of critical antimicrobials. Pilot new payment and reimbursement mechanisms that enable appropriate patient access to antimicrobials.

**APPROPRIATE USE**

- Continue to engage stakeholders, including the general public, to raise awareness on AMR and appropriate use. This includes scaling up educational activities and promoting the use of smarter prescription tools that are adapted to local contexts. It also includes providing timely and accurate microbiological data.
- Increase sharing of AMR surveillance data by Alliance members and support initiatives to increase public reporting of infection rates, antimicrobial resistance patterns, and antibiotic use.
- Encourage Alliance members to share best practice and align product-related promotional activities with the goal of supporting appropriate use.
- Strengthen external stakeholders’ awareness of the critical role that diagnostics and vaccines have in supporting antimicrobial stewardship.
- Encourage Alliance members to engage in more activities for appropriate use, including increased work on IPC and WASH. This includes sharing best practices, for example, through independent educational webinars and research grants.

**MANUFACTURING & THE ENVIRONMENT**

- Accelerate implementation of the common manufacturing framework across members’ supply chains, and encourage Alliance members to take appropriate action to address facilities that do not meet expectations.
- In light of relevant scientific advances periodically update PNECs as new data become available and consider developing further technical guidance to support broader risk assessments (e.g., for solid wastes and other antimicrobials).
- Review anticipated PNEC adherence to better understand members’ projections and, where appropriate, explore mechanisms to encourage faster progress.
- Determine the relative merits of self-assessment compared with independent third-party assessment against Alliance standards.
- Leverage the Alliance’s expertise to engage and inform regulators as a means to support appropriate oversight of antimicrobial manufacturing.
REFERENCES


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.

Chemin des Mines 9, P.O. Box 195
1211 Geneva 20, GE 1211 Switzerland
Tel: +41 22 338 32 00 | Fax: +41 22 338 32 99 | info@amrindustryalliance.org

ABOUT SUSTAINABILITY

SustainAbility is a think tank and strategic advisory firm which for 30 years has worked to inspire and enable business to lead the way to a sustainable economy. SustainAbility works with the life sciences industry on global health, corporate responsibility and sustainability topics.

sustainability.com