

GLG Barbados Meeting

James Anderson, Executive Director of Global Health at IFPMA, and AMR Industry Alliance Chair



Declaration by the Pharmaceutical,
Biotechnology and Diagnostics
Industries on Combating
Antimicrobial Resistance



amr INDUSTRY ALLIANCE
UNITED AGAINST ANTIMICROBIAL RESISTANCE

AMR Industry
Alliance 2021
Survey

The increase in bacterial resistance to antibiotics has been dramatic, and combating this growth is a top priority for global public and public health. There is a particular concern that antibiotics are losing effectiveness faster than they are being replaced by innovative drugs, including both antibiotics and alternative non-antibiotic

This innovation gap has been examined extensively and is widely acknowledged to be the result of a combination of scientific as well as commercial barriers that have impeded antibiotic development over a number of years. The scientific difficulties are formidable and traditional R&D approaches have largely failed; companies, private and public funders have invested billions of dollars over the last 20 years to discover new antibacterials, yet no new class of antibiotic for Gram-negative infections has reached approval in over 40 years.

This situation poses a unique set of challenges. We will need to develop innovative new antibiotics; all antibiotics need to be used cautiously to conserve their effectiveness; and, in many countries, we still need to improve access to existing antibiotics.

We welcome economic analysis of the costs and investments needed to develop AMR, which quantifies both the costs and investment changes from many stakeholders, clearly substantial and call for transformational changes from many stakeholders in pharmaceutical, biotechnology, and diagnostics industries have an important role to play, and we are committed to doing our part. Leadership from other sectors is required, and we welcome the initiative of the Review on AMR, as well as the efforts of governments and politicians world-wide (including the recent G7 Berlin declaration) and international organisations (WHO, GIE, FAO, ECDC, US CDC, and others).

public funding bodies (NIH, BARD, the European Commission, and many others), and private foundations (Wellcome Trust, BMGF, and Pew Charitable Trusts)*, amongst others. We similarly welcome those steps already taken by key regulatory authorities (FDA and European Medicines Agency) and the Food and Drug Administration (FDA) and European Medicines Agency (EMA) to support the development of new drugs and medical devices.

the world, such as the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA), to enable antibiotic development in advance of widespread resistance. We support a continuation of these efforts to ensure greater harmonisation of regulatory processes internationally.

Antibiotic manufacturing standard

Minimizing risk of developing antibiotic resistance and aquatic ecotoxicity in the environment resulting from the manufacturing of human antibiotics



Global Principles on Incentivizing Antibiotic R&D



2021 AMR Preparedness Index



Global
Coalition
on Aging

IDS A

Why we need action

Antibiotic Pipeline is weak....and mortality is high

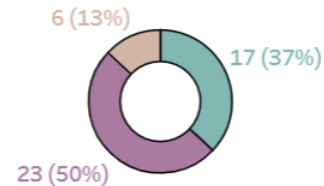
A.3. Products by pathogen category and phase

Pathogen category	Phase I	Phase II	Phase III	Preregist..	Total
Priority pathogens	16	3	8	1	28
Mycobacterium tuberculosis	6	7			13
Clostridioides difficile		4	1		5
Total	22	14	9	1	46

C.1. Innovative?

Innovative?

Yes
No
Inconclusive



C.1. Innovative? Phase 3 only



*Source: [Pipeline of antibacterial products in clinical development \(who.int\)](#); [AMR clinical pipeline June2022 | Tableau Public](#)

Bridging the AMR R&D clinical funding gap

2020



2022

In April 2022, the AMR Action Fund announced its first two investments.



adaptive phage
THERAPEUTICS

2023

In January 2023, the AMR Action Fund announced its third investment.



Responding to the clinical AMR R&D funding gap, a bridging **\$1 billion AMR Action Fund** is established in partnership with WHO, Wellcome Trust, and the European Investment Bank. Over 20 large IFPMA member pharmaceutical companies invested, and funding was also provided by the European Investment Bank and the Wellcome Trust.

The life-sciences industry is also working to holistically address the challenges of AMR

Established 2017



In 2022, the AMR Alliance released its 3rd Progress Report, showcasing progress of the life-sciences industry across its focus areas.

In FY 2019 and 2020, Alliance member companies **invested between 1.8 and 1.9 billion USD into AMR R&D** – but these investment levels are threatened.



Four out of five (81%) surveyed companies reported being active in supporting access to AMR-relevant products and/or technologies. Implementation of appropriate use and stewardship activities were also reported as a major focus of companies, with 92% of R&D pharmaceutical companies, 89% of generics companies, and 80% of diagnostics companies having taken such actions.

Alliance progress in 2022



- The Alliance published its **Antibiotic Manufacturing Standard**, which provides clear guidance to manufacturers in the global antibiotic supply chain to ensure that their antibiotics are made responsibly.
- The Alliance **commissioned a report on the sustainability of the off-patent supply chain** to gain insight into the root causes of supply chain instability among off-patent antimicrobials and identify potential policy solutions to address these issues. The report will be published in February 2023.
- The Alliance commissioned a report by the One Health Trust on drug regulatory approvals and opportunities for antimicrobial innovation, describing the current climate for antimicrobial innovation, focusing on regulatory pathways, and **providing recommendations to accelerate the approval of antibiotics in emerging markets (Brazil, India, and South Africa as case studies)**.
- The Alliance **awarded its second annual stewardship prize to Lekma Hospital in Ghana and the Clinical Engagement Program in Pakistan, led by DAI**. The yearly Stewardship Prize acknowledges organizations' innovative approaches to AMR stewardship in their communities, with the goal of highlighting best practices and inspiring examples.

Alliance ambition in 2023



- Alliance members have shown their willingness to self-regulate by developing the AMRIA Manufacturing Standard and are **working with British Standards Institution (BSI) to develop an independent certification scheme**. In addition, the Alliance **will continue to work to drive widespread adoption of the Standard across the industry** to significantly reduce AMR risk from antibiotic manufacturing, contributing to the overall reduction of environmental AMR risk.
- **BD, BioMerieux, Pfizer, and the Alliance supported a Wellcome Trust project that assessed diagnostics' effectiveness in improving antimicrobial stewardship programs.** The research team recently submitted a preliminary summary of the findings to ECCMID.
- The Alliance is working on a whitepaper on the role of diagnostics in NAPs. **The whitepaper will highlight the necessity to include diagnostics in NAPs** and increase awareness of diagnostics' important role in stewardship and appropriate use.
- The Alliance is working on a report on the human resources shortage in the field of antimicrobial R&D, aiming to **evaluate the current state of the antimicrobial researcher workforce and consider ways to ensure its sustainability moving forward.**



Thank you

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