

Appendix to the IFPMA *Global Principles on Incentivizing Antibiotic R&D*

The Burden of AMR in Brief

The use of antimicrobials to treat and prevent infections has enabled almost all of modern medical innovation today, underpinning procedures such as organ transplantation, cancer chemotherapy, major surgery, and the care of preterm infants and immunocompromised patients.

Drug resistant infections are estimated to cause approximately 700,000 deaths worldwide each year¹. The World Bank estimates that drug-resistant infections have the potential to cause a level of economic damage similar to—and likely worse than—that caused by the 2008 financial crisis². Estimates suggest a \$100 trillion GDP loss between now and 2050¹. In OECD countries, hospitals spend, on average, an additional USD 10,000 to 40,000 to treat a patient infected by resistant bacteria³. The associated impact of lost economic output due to increased mortality, prolonged sickness and reduced labor efficiency could double this figure.

The Centers for Disease Control and Prevention (CDC) estimates at least 48,000 deaths and 3 million infections in the U.S. from pathogens on its 2019 AMR Threats list. The CDC estimates just 8 of the 16 pathogens on list represented \$5.75 billion dollars in direct healthcare costs in 2017⁴. In Europe, each year, AMR is responsible for about 33,000 deaths and costs about €1.1 billion to the health care systems of EU/EEA countries⁵.

According to the WHO 2019 Clinical Pipeline⁶, the current pipeline contains 38 antibiotics and combinations (with a new therapeutic entity)*, and 10 biologicals, of which 32 antibiotics are active against the WHO priority pathogens. Pew Trusts reports, as of December 2019, 41 antibiotics in development⁷, of which likely only a handful will reach the market. Of 41, at least 18 in development have the potential to treat Gram-negative ESKAPE pathogens. Approximately 1 in 4 drugs in the pipeline represent a novel drug class or mechanism of action. Pew Trusts also reports another 21 non-traditional antibacterial products† currently in clinical development⁸. Another 12 antifungal agents⁹ are currently in clinical development.



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*An additional 12 antituberculosis agents were identified.

† 'Non-traditional' includes antibodies, live biotherapeutic products, antibiotic inactivators, lysins and immunomodulators. An additional 9 vaccines were identified.

AMR Action Fund

Over 20 leading pharmaceutical companies launched a ground-breaking partnership to invest nearly \$1 billion through a new AMR Fund¹⁰ that aims to bring 2 to 4 new antibiotics to patients by the end of the decade – treatments that otherwise would be unlikely to get the funding needed to complete development. The AMR Action Fund seeks to:

- Bridge the AMR funding gap in development: ‘push’ funding from governments and charities has boosted early stage research, but the key gap is in the clinical phases.
- Strengthen the antibiotics research and development ecosystem through the provision of industry resources and knowledge.
- Create a unique, collaborative platform with the pharmaceutical industry, multilateral development banks, philanthropic funders and strategic partners, to facilitate the necessary policy reforms to create an environment that encourages long-term investment into antibiotic R&D.

The AMR Action Fund will invest mainly in smaller biotech companies focused on developing novel antibiotics that address the highest priority public health needs, make a significant difference in clinical practice, and save lives. Our investments will be guided by an independent Scientific Advisory Board comprised of world-class experts. The Fund will:

- Focus on investment in assets centered around the WHO/CDC priority lists of pathogens, with the goal to address major unmet needs and maximize public health impact.
- Prioritize investment in novel treatments of bacterial infections.
- Focus on “novel” antibiotic treatments, as recognized by leading public health agencies, with significant and differentiated clinical utility and that reduces patient mortality.
- Invest across the most complex and expensive later stages of clinical development.



In 2020, over 20 leading pharmaceutical companies launched a ground-breaking partnership to invest nearly \$1 billion through a new AMR Fundⁱ that aims to bring 2 to 4 new antibiotics to patients by the end of the decade.

AMR Industry Alliance

In 2016, over 100 companies from the life-sciences industry (R&D, generics, diagnostics, and biotech companies) signed the Industry Declaration on AMR at the World Economic Forum, followed by the launch of a Roadmap in September 2016 at the time of the UN High Level Meeting on AMR. Leveraging this common set of principles for global action, including on investing in R&D to meet public health needs, companies involved subsequently formed the AMR Industry Alliance to drive and report progress of the life-sciences industry against its broader commitments in tackling AMR. At the end of 2018, the Alliance revised its set of commitments and metrics to better reflect the developing global discussions on AMR, and the progress achieved by the Alliance.

In January 2020, the Alliance published its second Progress Report, presenting progress of member companies against the four areas of Alliance commitments:

- Investing into Research & Science to prevent and treat resistant infections
- Working to improve the Access to AMR treatments for patients who need them world-wide
- Improving the Appropriate Use of AMR treatments through surveillance, supporting measures for the prevention of infection and comprehensive stewardship programmes, as well as encouraging that local clinical guidelines are kept up-to-date
- Reducing any discharges from antibiotic Manufacturing into the Environment

Progress is recorded through detailed metrics in each of these areas, as applicable to Alliance subsectors.

The second progress report revealed, among others¹¹:

- The Alliance has taken a leadership role in responsible manufacturing of antibiotics, establishing an industry standard for reducing potential environmental risks from antibiotics production (the Common Antibiotic Manufacturing Framework and the list of predicted no-effect concentrations).
- In 2018, Alliance members collectively invested more than \$1.6bn into the development of AMR-relevant products. Eighty-four percent of relevant companies are engaged in late-stage R&D, or have at least one AMR-relevant product/platform in clinical development.
- The majority of respondents reported having developed comprehensive strategies to improve access and revising promotional activities to align with antimicrobial stewardship.
- Next steps of the Alliance include sharing R&D information to support innovation and surveillance data to track resistance, deploying diagnostics and vaccines in support of improved appropriate use and working with health authorities to tackle antibiotic shortages.



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Endnotes

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