

GLOBAL CHALLENGES

THE GLOBAL AMR RESPONSE

OUR VISION

All infections are treatable
for everyone, everywhere

OUR MISSION

We accelerate **the development and access to treatments** for drug-resistant bacterial infections



ANTIMICROBIAL RESISTANCE HAS REACHED A TIPPING POINT

Despite significant global investment over the last decade, international efforts to stop the rise and spread of drug-resistant infections are no longer working. Antimicrobial resistance (AMR) is already one of the world's biggest killers, associated with 4.7 million deaths each year. And now the latest research suggests that this global crisis has reached an alarming tipping point. Experts anticipate a sharp rise in the number of AMR-related deaths, which are expected to increase by more than 70% by 2050.

The reason for this sudden surge is primarily the rise and spread of difficult-to-treat Gram-negative infections, combined with a lack of access to effective antibiotics across the globe. A radical shift in the global response is therefore needed, with significant investment in improving access to antibiotics globally and in the development of new and improved treatments to replace those lost to resistance. We cannot continue to successfully treat these kinds of infections with the antibiotics we have today and if people don't get the treatments they need.

A RADICAL SHIFT IS NEEDED

Until now, the global AMR response has focused primarily on three main approaches. The first lies in the stewardship or restriction of how antibiotics are used, both in human medicine and agriculture. Stewardship is essential in order to address one of the main drivers of drug resistance: the overuse and inappropriate use of antibiotics.

The second is prevention, which can reduce the rise and spread of AMR. Infection prevention and control (IPC) measures in healthcare and improved water, sanitation and hygiene (WASH), for example, are essential to reduce the transmission of bacterial infections. Similarly, by preventing infections from occurring in the first place, vaccination has helped prevent more than 500,000 AMR-related deaths a year.

The third is to stimulate R&D by providing financial incentives to pharmaceutical companies. In the face of the antibiotic R&D pipeline drying up, with many pharmaceutical companies withdrawing from the market, such "pull" incentives are considered by some to be critical in order to draw industry back and encourage the development of much-needed new antibiotics.

All three of these strategies have had some level of success and will continue to play an important role in addressing the rise and spread of AMR. However, given the rise of difficult-to-treat infections and the fact that more people are now dying from a lack of access to antibiotics than from drug resistance, it is now clear that by themselves they will not suffice for the future. Diminishing returns should be expected unless there is a radical shift towards solutions that prioritize tackling major drug-resistant pathogens, alongside the major barriers that impede access.

GARDP IS RESHAPING THE ANTIBIOTIC R&D MODEL

Such solutions are the focus of our work at the Global Antibiotic Research & Development Partnership (GARDP), namely the development of new antibiotic treatments that target World Health Organization priority

pathogens - multidrug-resistant infections that pose the greatest threat to public health - and improving access to essential antibiotics. In terms of lives saved and slowing the rise and spread of AMR, these are two interventions that will now have the greatest impact on people's health. Improving access alone is expected to prevent more than 50 million deaths by 2050.

GARDP was created to deliver on these objectives by harnessing the existing contributions of its partners in the public and private sectors. It does this by reshaping the traditional antibiotic R&D model, prioritizing public health impact, affordability and appropriate solutions for high-burden countries, in order to ensure that much-needed antibiotics are developed and reach the people in greatest need. That is why our clinical development efforts prioritize high-burden countries and populations, such as newborns, with access-related considerations integrated throughout the process. The aim is to create a robust portfolio of treatments that meet the needs across key disease areas (See "GARDP Programmes").

GARDP's not-for-profit model makes it possible for antibiotics to be tested in the high-burden countries where they are most needed, for them to be registered and marketed early in those same countries, while also creating a more viable economic model for antibiotic development. In many high-burden countries, the regulatory, post-approval and commercialization processes have the potential to be more cost-effective, given higher patient numbers and volumes. In parallel, the sustainable development of different pharmaceutical formulations becomes feasible because GARDP helps to de-risk the process. All this makes it possible to achieve affordability while still enabling our pharmaceutical and manufacturing partners to earn commercial revenues.

This unique public-private partnership approach essentially creates a new antibiotic R&D ecosystem, which factors in equitable access at every stage. This makes it possible to ensure that the antibiotic treatments that are most needed are not only developed but also reach the people in greatest need. These are the most urgent priorities moving forward, to reverse the trajectory of drug-resistant infections. Just as resistance continues to evolve, so must the global AMR response.

GARDP'S UNIQUE MODEL

GARDP's unique public-private partnership model is based around three principal approaches:

Integrated R&D and access

- In addition to GARDP's dedicated access programme, access is factored into every stage of our drug development process, from scientific discovery and R&D, right through to manufacturing, registration and commercialization.

Manufacturing and license agreements

- Through our innovative use of licensing agreements with pharmaceutical companies and manufacturers, we can reduce much of the economic risk associated with developing these drugs, while enabling manufacturers to produce them at profit.

Equal partnerships

- The success of our model hinges upon the fact that we work through fair partnerships, working with key stakeholders both in high-income countries and LMICs – including scientists, clinicians, industry, manufacturers, governments, donors and civil society – to coordinate efforts, expertise and resources.

GARDP PROGRAMMES

1 DRUG DEVELOPMENT & ACCESS

SERIOUS BACTERIAL INFECTIONS

- cefiderocol
- BWC0977 (IV and oral)
- apramycin

NEONATAL SEPSIS

GARDP is comparing new and existing treatment combinations including:

- fosfomycin-amikacin
- flomoxef-amikacin
- fosfomycin-flomoxef

SEXUALLY TRANSMITTED INFECTIONS

- zoliflodacin
- Debio 1453

2 DISCOVERY & EXPLORATORY RESEARCH

- Identifying promising small-molecule candidates, prioritizing those active against *Acinetobacter baumannii* and multidrug-resistant *Klebsiella pneumoniae*.

3 SCIENTIFIC AFFAIRS & REVIVE

CONNECTING THE R&D COMMUNITY

 **REVIVE**
by GARDP

LEARN MORE: WWW.GARDP.ORG