GARDP

Global Antibiotic Research & Development Partnership

GLOBAL CHALLENGES

THE GLOBAL AMR RESPONSE

OUR VISION

All infections are treatable for everyone, everywhere

OUR MISSION

We accelerate **the development and access of 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 and associated with 4.7 million deaths each year. But now the latest research suggests that as this global crisis continues to worsen it has reached an alarming tipping point. With mortality having remained relatively stable in recent decades we should now expect a sharp rise, with the number of AMR-related deaths increasing by more than 70% by 2050.

The reason for this sudden surge is the rise and spread of difficult-to-treat Gram-negative infections and a lack of access to effective antibiotics across the globe. A radical shift in the global response is therefore needed, with significant investment towards 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.

THE GLOBAL AMR RESPONSE WILL NO LONGER WORK

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 has also proved to be an incredibly effective way of reducing the rise and spread of AMR. Infection prevention and control (IPC) measures 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 antibiotics 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 these two issues.

A RADICAL SHIFT IS NEEDED: GARDP IS FLIPPING THE ANTIBIOTICS R&D MODEL

Such solutions include the focus of our work here 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 which will now have the greatest impact. Improving access alone is expected to prevent more than 50 million deaths by 2050.

GARDP was created to deliver on both these objectives by harnessing the existing contributions of its partners in the public and private sectors. It does this by flipping the traditional antibiotics R&D model, prioritizing public health impact, affordability and high-burden countries, in order to ensure that the antibiotics most needed are developed and reach the people in greatest need. That is why our clinical development efforts are focused on high-burden countries and high-burden populations, such as newborns, with access-related considerations integrated throughout the process, with the aim of creating a portfolio of treatments 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, and for them to be registered and marketed early in those same countries. Prioritizing high-burden countries requires a development pathway focussed on registering in those countries and addressing the AMR burden, while also creating a more viable economic model for antibiotic development. In these countries the regulatory, post-approval and commercialization processes have the potential to be more cost-effective, with 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, and enables our pharmaceutical and manufacturing partners to earn commercial revenues.

This unique public-private partnership approach essentially creates a new antibiotics R&D ecosystem, and one which has equitable access factored into it at every stage. This makes it possible to ensure that the antibiotic treatments that are most needed are developed and reach the people in greatest need. With AMR having now reached such a critical tipping point, these must be the new priorities moving forwards. Because 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 principle approaches:

- **Integrated R&D and Access**

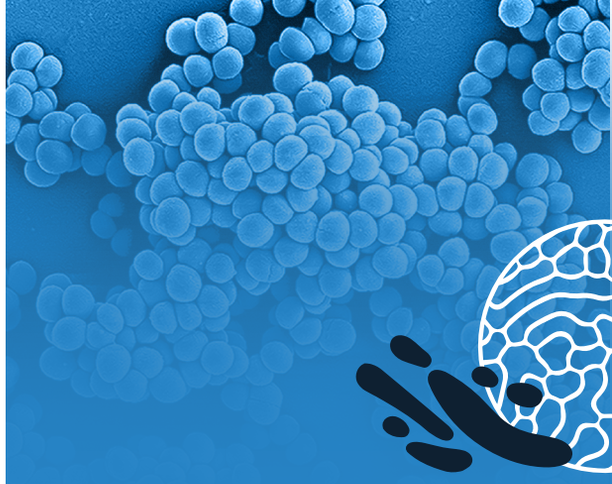
  In addition to GARDP's Access programme, access is factored into every stage of the drug development process, from scientific discovery and R&D, right through to the manufacturing, registration and last mile delivery of antibiotics.

- **Development and license agreements**

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

- **Fair 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 & SEPSIS
- cefiderocol
- cefepime-taniborbactam
- BWC 0977

NEONATAL SEPSIS
- fosfomycin-amikacin
- flomoxef-amikacin
- fosfomycin-flomoxef

SEXUALLY TRANSMITTED INFECTIONS
- zoliflodacin

2 DISCOVERY & PRECLINICAL RESEARCH

DISCOVERY & EXPLORATORY RESEARCH

3 ACCESS TO ESSENTIAL ANTIBIOTICS

secure

4 CONNECTING THE R&D COMMUNITY

SCIENTIFIC AFFAIRS & REVIVE

REVIVE by GARDP