GARDP

Global Antibiotic Research & Development Partnership

GLOBAL CHALLENGES

ANTIBIOTIC ACCESS

**4.71 million deaths**
associated with antibiotic-resistant infections

**80%** of deaths occur in LMICs

BARRIERS TO ACCESS

**EVIDENCE FOR OPTIMAL USE**
incomplete/non-existent

**MARKET**
unpredictable, fragmented, unclear and/or low volume

**SUPPLY**
inadequate and vulnerable

**REGISTRATION**
limited, especially in low- and middle-income countries

**DISTRIBUTION**
insufficient

**PLANS**
to introduce and use products are underfunded and incomplete

# CHALLENGES TO SUSTAINABLE ACCESS FOR AMR TREATMENTS

**Sustainable access to antibiotics is a critical component in the global response to the escalating crisis of antimicrobial resistance (AMR). The current situation is dire, with 4.71 million deaths associated with antibiotic-resistant infections, 80% of them in low- and middle-income countries (LMICs). More than 50 million deaths could be prevented by 2050 if both existing and newly developed antibiotics that are effective against multidrug-resistant infections, were made accessible to more people in need.**

**Access is often interpreted as meaning the "last-mile" delivery of medical interventions, such as vaccines, antiretrovirals and bed nets, to patients at the point-of-care. The arrival of life-saving medical supplies can be hindered by a wide range of challenges including affordability, inferior quality, shortages, poor infrastructure and a lack of diagnostics and disease surveillance. While this is also true for antibiotics, there are additional barriers that prevent millions of people from getting the right antibiotics when they need them. These barriers can be traced right back through the entire antibiotic development process.**

## BARRIERS TO ACCESS

More often than not, when new antibiotics first enter the market, they are only registered in a handful of wealthy nations and are priced out of reach for LMICs. Between 1999 and 2014, less than half of the new antibiotics were registered in more than ten LMICs.

In the face of such challenges, many governments may see investment in preventative measures as the most immediate way to save lives and tackle AMR. Interventions like infection prevention and control (IPC), water, sanitation and hygiene (WASH) and vaccination play a critical role in reducing bacterial infections. But because it is impossible to prevent all infections, sustainable access to effective antibiotic treatments is vital too. Without it more lives will be lost and the spread of AMR will continue, making infections increasingly difficult to treat.

To overcome the barriers to sustainable access to existing and new antibiotics, an entire ecosystem approach is required, involving national, regional and global solutions. Countries must invest in their AMR National Action Plans (NAPs), which are often incomplete and unfunded. This will be important to build capacity and determine antibiotic needs.

Public-private partnerships have a central role to play in achieving this ecosystem shift. In doing so, they can also help to improve last-mile delivery as well as the predictability and efficiency of markets. The long-term commitment of private partners will ensure that meeting public health needs becomes the ultimate goal.

## GARDP'S APPROACH TO SUSTAINABLE ACCESS

A core part of GARDP's work focuses on improving access to effective antibiotics by removing barriers and helping countries to introduce them. We do this by working with local partners to carry out studies that will help fill vital data gaps in disease surveillance and identify the antibiotic needs of key high-burden countries. We also work with regulatory authorities to accelerate the registration of antibiotics.

Part of this involves carrying out catalytic market shaping activities, using demand forecasting, pooled procurement, stockpiling and volume guarantees to help make GARDP portfolio antibiotics affordable and available. By working with ministries and local experts, we also carry out introduction studies that will be helpful for AMR National Action Plans. This will ultimately increase access by improving in-country delivery of antibiotics.

In addition to all this, sustainable access is also factored into everything else GARDP does. By working on every stage of antibiotic development, from scientific discovery and R&D to supporting the manufacturing, registration and introduction of treatments, our aim is to create an ecosystem that ensures improved access to effective new and essential antibiotics.

Focusing on antibiotic treatments with the highest public health value, we don't just fund clinical trials, we actually carry them out. This allows us to ensure antibiotic treatments are tailored to specific populations, including those that are often excluded from clinical trials, such as newborns, women and people living with HIV.

In addition this GARDP's unique integrated R&D and access model makes use of innovative licensing agreements and market shaping activities for the manufacture and distribution of the effective antibiotics that we co-develop. This enables us to ensure they are safe, affordable and suitable for use for all populations especially in high-burden, resource-limited settings, making them accessible to those who need them most.

secure
*The Antibiotic Facility*

Part of GARDP's work focuses on improving access to existing antibiotics through SECURE, a partnership with WHO. This collaboration supports sustainable, equitable, and appropriate access to priority antibiotics in LMICs. Improving efficiencies in forecasting, procurement, and supply will improve decision-making, reduce shortages, and identify priorities for local manufacturing. SECURE has developed a forecasting and economic model to incentivize suppliers by illustrating the benefits of pooling, stockpiling, supplier guarantees, and country subsidies. This will improve supply security, demand predictability, availability, and affordability of these antibiotics.

## OUR VISION FOR ACCESS

**DISSEMINATING BEST PRACTICES**
**Develop and disseminate** best practices on antibiotic access

**ENSURING ACCESSIBILITY**
Facilitate **available, affordable, and appropriate access** to GARDP's portfolio of products

**DEFINING ACCESS PATHWAYS**
Develop and demonstrate diverse access models, using portfolio products as **"pathfinders"**

**ENABLING PARTNERSHIPS**
**Enable partnerships** to strengthen the global AMR access ecosystem, including drug optimisation, pooled procurement and stewardship initiatives

To continue this progress and improve access to antibiotics, GARDP requires

**€ 43.7 million**

over the period 2024-2028

## PATHFINDER

A prime example of how GARDP is improving access to antibiotics is through its work on accelerating access to cefiderocol. Developed by the Japanese pharmaceutical firm Shionogi, cefiderocol has been identified by GARDP as a potentially important antibiotic to help stop the rise and spread of AMR. It was first approved for the treatment of complicated urinary tract infections in 2019, and has been shown to be active against multidrug-resistant Gram-negative bacteria classified as critical in the World Health Organization's priority pathogens list, including those that are resistant to carbapenem antibiotics.

Like most new antibiotics when they are first developed, cefiderocol is only available in a handful of high-income countries. In LMICs, access to Reserve antibiotics like cefiderocol would normally be delayed by more than a decade, if they get access at all. GARDP is now changing that through its innovative use of licensing and technology transfer agreements. This, together with its work on disease surveillance, demand forecasting, pooled procurement and stockpiling, will enable GARDP to manufacture and commercialize cefiderocol in up to 135 countries, including all low-income and lower-middle income countries. This accelerated access to cefiderocol could benefit nearly half a million people over ten years.