



## Global Antibiotic Research & Development Partnership

Antibiotic resistance is now one of the world's biggest causes of death. It is associated with nearly 5 million deaths a year, a number that is rising. One of the main reasons for this escalating global antimicrobial resistance (AMR) crisis is that the rise and spread of drug-resistant bacteria outpaces the development of new and effective antibiotics.

With the antibiotic pipeline in decline for decades, this is likely to continue and radically impact our ability to provide people with working treatments. Over the last century, antibiotics have transformed modern medicine and helped increase life expectancy by 23 years. But this progress is now being reversed because of AMR, with a 1.8 year fall in life expectancy predicted by 2035. As antibiotics lose their effectiveness, infections are becoming increasingly untreatable, making once minor infections and medical procedures become life-threatening or cause serious illness. People in low- and middle-income countries (LMICs) are most at risk, as are children and newborns. One in 5 deaths associated with drug-resistant infections occur in children under the age of 5, and 99.2% of these are in LMICs.

### GARDP aims to develop and provide access to treatments for drug-resistant infections

The Global Antibiotic Research & Development Partnership (GARDP) was created as a global solution to the growing threat of AMR. GARDP aims to:

- accelerate the development of new and effective antibiotics against bacteria that pose the greatest threat to public health;
- improve access to essential antibiotics (both newly developed and those that already exist).

To significantly reduce mortality and morbidity related to drug resistance around the world, GARDP has developed a disease area strategy based on three criteria: 1) priority diseases and infections, including sexually transmitted infections (STIs) and serious bacterial infections and sepsis, including neonatal sepsis; 2) the deadliest drug-resistant bacterial pathogens; and 3) regional needs and vulnerable populations, including children, pregnant women and the older people. Its new strategy focuses on putting public health needs at the centre of antibiotic drug development ecosystem, ensuring that the right antibiotic treatments are made available to people who need them, particularly in LMICs.

### Sexually transmitted infections

With STIs, for example, GARDP is working with partners to develop a new first-in-class antibiotic for the treatment of drug-resistant gonorrhoea infections. With 82 million infections a year, drug-resistant *Neisseria gonorrhoeae* is on the rise and included on WHO's list of priority pathogens in urgent need of new treatments. In addition to this, GARDP is considering the development of a new antibiotic treatment for difficult-to-treat gonorrhoea and other STIs, like *Mycoplasma genitalium* and syphilis.

### Serious bacterial infections and sepsis

GARDP also aims to develop new antibiotic treatments for serious bacterial infections (SBIs) that are multidrug-resistant. SBIs are a major cause of sepsis, which kills 11 million people a year. This work is also focused at improving access by developing treatments that are optimised for use in LMICs and vulnerable populations, including generating evidence that will support the development of

guidelines for the treatment of SBIs leading to sepsis in LMICs. As newborns are especially vulnerable to sepsis, and since few existing antibiotics are formulated for them, GARDP is aiming to accelerate the time it takes to make new treatments available. GARDP does this by focusing on combinations of existing antibiotics for this life-threatening bloodstream infection.

### Improving sustainable access

Developing new drugs alone will not fully address the antibiotic resistance crisis; people also need sustainable access to them. So, in addition to the development of new and effective antibiotics to replace those that no longer work, GARDP is committed to ensuring that people in all corners of the world can get access to these antibiotics – both newly developed as well as existing ones.

GARDP factors access into every stage of antibiotic development, from scientific discovery and R&D to supporting the manufacturing, registration and introduction of treatments.

As a public-private partnership, GARDP works with global partners to facilitate global registration of antibiotic treatments, as well as guidelines for appropriate use and stewardship of antibiotics. By supporting countries with the development of access plans for specific antibiotic interventions, in part by conducting implementation research and in-country demonstration projects, the organisation is also helping countries to improve access.

More specifically, GARDP is working with partners to develop access pathways to treat serious bacterial infections and sepsis, using cefiderocol as a 'pathfinder'. This is an antibiotic recently approved for use in the United States and Europe. It is active against many of the bacteria for which there are few or no other alternative treatments in many LMICs. However, cefiderocol is not available in any LMIC yet. GARDP aims to identify and remove any barriers to LMIC access to this drug, with lessons learnt applied to ensure sustainable access to other treatments for drug-resistant infections.

### Focus on the needs of women and girls

Women and girls face disproportionately high health risks due to a lack of access to sexual and reproductive health services. Untreated gonorrhoea can cause serious health problems in both women and men. But for women, gonorrhoea may lead to infertility and the infection can be passed on from mother to child while giving birth. GARDP has designed its STI studies, including those on new gonorrhoea drugs, to incorporate participation of more women, who are normally excluded from trials.

GARDP's focus on gonorrhoea will directly improve sexual and reproductive health, which includes helping women have a healthy pregnancy, safe birth and healthy babies.

### Working together to counter AMR

As a public-private partnership, GARDP is built around collaboration and has created a global network of partners for antibiotic product development, R&D and access activities. Many of its partners are based in LMICs, such as India and South Africa,

acknowledging the importance of in-country expertise on local resistance patterns and LMIC-based clinical trials. In The Netherlands, GARDP works with the Public Health Services of Amsterdam (GGD Amsterdam).

### Budget

Cost of activities:	€ 209,448,845
Contribution by the Netherlands Ministry of Foreign Affairs (PDP IV Fund):	€ 14,350,000

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### Product Development Partnerships IV Fund - PDP IV

The Product Development Partnerships IV Fund (PDP IV) promotes the development and accessibility of healthcare products. Specifically, PDP IV targets diseases and conditions related to poverty and sexual and reproductive health and rights (SRHR). The fund focuses on the development and availability of more effective, safe, affordable, and demand-driven medicines, vaccines, diagnostics, and other products. Women and girls between the reproductive ages of 15 to 49 in Low-Income Countries (LICs) and Middle-Income Countries (MICs) are the main target group.

### About RVO

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