Global Antibiotic Research and Development Partnership (GARDP)

UN Global Leaders Group Briefing
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Public and philanthropic funding for late-stage R&D development is inadequate

Only 20% of funding goes to late-stage drug development.

Total therapeutic investments in million USD by R&D stage (source: 2020 Global AMR R&D Hub Report)
Two trends in antibiotic access

1. Not widely registered

Number of antibiotics registered 1999-2014

2. Growing antibiotic resistance

Carbapenem-resistant *Acinetobacter baumannii*

Carbapenem-resistant *Klebsiella pneumoniae*
All infections are treatable for everyone, everywhere

Our Mission

We work with partners to accelerate the development and access to treatments for drug-resistant infections
Tackling antibiotic resistance together

A global organization working with 70 partners across 16 countries including governments, academic institutions, civil society and the private sector.
GARDP in the AMR Landscape

Non-profit initiatives

Basic research

Discovery / Preclinical / Phase 1

Late-stage clinical development

Post-registration studies & access

Private funders

US Government funders

*Illustrative not exhaustive
Benefits of a not-for-profit model

• Investment in projects with little or no commercial value, but fulfilling a public health need

• Focus on populations, including children, and geographies worldwide for R&D with a public health perspective

• Less risk averse

• Perceived as a neutral, trusted partner by the public and private sectors

• Motivation and capacity to mobilize resources to foster R&D and access infrastructure
Addressing the most urgent threats to public health

**Sepsis in children and newborns**
1 in 5 deaths due to antibiotic resistance occur in children. 140,000 newborns die each year.

**Serious bacterial infections in adults**
Patients undergoing common medical procedures, such as C-section, hip replacement, or chemotherapy, are at risk of acquiring bacterial infections that cannot be easily treated with commonly used antibiotics.

**Sexually transmitted infections**
Sexually transmitted infections caused by bacteria may become untreatable with the rise of superbugs, especially gonorrhoea.
Our programmes

1. Antibiotic research & development
   Developing new antibiotic treatments to address the most urgent public health threats

2. Accelerating access
   Securing access to a portfolio of novel and generic antibiotics for all people, everywhere

3. REVIVE
   Preserving and sharing scientific knowledge
Children’s antibiotics

3 potential combination treatments for neonatal sepsis
Completed one of the largest studies on babies with sepsis—3,200 newborns in 11 countries—and identified 3 promising antibiotics for use in combination (amikacin, fosfomycin, and flomoxef)

Public health trial to test treatment combinations
A multinational trial of new antibiotic combinations to treat neonatal sepsis should recruit the first patients in Feb/Mar 2023

Paediatric studies of new antibiotics
Supporting paediatric studies for cefepime-taniborbactam

Provide new treatment options for 20 million children (including 3 million newborns) with sepsis and help prevent up to 3 million deaths each year

HOW?
By obtaining paediatric indications, sharing global recommendations on treatment options and dosage, and facilitating access to new—and the right—antibiotics
Sexually transmitted infections

• Phase 3 zoliflodacin trial participating countries

TODAY

A new innovative treatment for gonorrhoea in late-stage development (zoliflodacin)

GARDP and Entasis are finalizing a global phase 3 trial in 16 sites across 5 countries to evaluate zoliflodacin, an innovative oral treatment for gonorrhoea.

The final trial results will become available in the course of 2023.

Completed the manufacturing of the final drug product for registration and commercialization.

TOMORROW

Provide a new oral treatment option for 82 million people who contract gonorrhoea each year and limit its global spread.

HOW?

By expanding access to this new treatment, upon approval, in countries around the world.
A promising new antibiotic treatment on track for regulatory submission (cefepime-taniborbactam)
Welcomed positive results in a phase 3 trial of cefepime-taniborbaactam by Venatorx Pharmaceuticals. If approved, this will be the first antibiotic treatment to be launched in collaboration with GARDP.

An approved antibiotic treatment (cefiderocol)
Signed an agreement with Shionogi and CHAI to facilitate access to this new antibiotic in 135 countries, mostly low- and middle-income countries.

An observational study of priority pathogen infections in hospitalized patients in high priority countries
Launching an observational study at 11 sites across India and South Africa to record current treatment practices for infections caused by carbapenem resistant infections.

TODAY

HOW?
By developing new antibiotic treatments and making them accessible to anyone who needs them.

TOMORROW

Provide new treatment options for 29 million adults with sepsis and help prevent up to 8 million deaths each year.
Accelerating access

TODAY
Access agreements with:
• Groundbreaking license agreement with Shionogi to make an antibiotic (cefiderocol) accessible in 135 countries, mostly low- and middle-income countries (LMICs)
• Venatorx Pharmaceuticals for a new antibiotic combination (cefepime-taniboractam) in 66 LMICs upon approval
• Entasis Therapeutics for a new gonorrhoea antibiotic (zoliflodacin), upon approval, in all LMICs (150)

A global access initiative: SECURE
A joint initiative by WHO and GARDP in collaboration with UNICEF and CHAI to accelerate access to essential antibiotics for countries in need

Policy support
Supporting policies to address antibiotic shortages and add existing antibiotics – such as flomoxef – to the WHO Essential Medicines List

TOMORROW
Provide equitable access to effective antibiotics for everyone, everywhere

HOW?
By working with medical professionals, policymakers, antibiotic developers, non-profit groups and others to expand antibiotic access in a responsible way
The cefiderocol access project: A comprehensive approach to access

An agreement signed with Shionogi and CHAI to improve access to cefiderocol in 135 LMICs is paving the way for sustained access to this and other antibiotics.

**Manufacturing**
Affordable and quality-assured products from a licensed manufacturer

**Registration**
Support for commercialization in high-burden countries

**Implementation**
Partnerships to co-develop and introduce robust implementation plans

**Guidelines**
Evidence-based guidance to steward appropriate use
SECURE: The Antibiotic Facility

A joint initiative of WHO and GARDP, with support from UNICEF and the Clinton Health Access Initiative, SECURE seeks to accelerate access to a portfolio of essential antibiotics, while ensuring their sustainable use.

A four-year pilot is expected to be launched in 2024 in participating countries.
# An overview of GARDP’s 5 treatments by 2025

<table>
<thead>
<tr>
<th>Disease area</th>
<th>GARDP programme area</th>
<th>Treatment</th>
<th>Target pathogens* (WHO priority pathogens)</th>
<th>Description</th>
<th>Investments to date (EUR)</th>
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</table>
| Sepsis       |                      | **Treatment 1:** neonatal sepsis empiric treatment regimen (Shionogi & Co., Ltd and InfectoPharm) | ESBL | Treatment for sepsis in newborns:  
  • flomoxef-fosfomycin  
  • fosfomycin-amikacin  
  • flomoxef-amikacin | 25 million |
| Sepsis       |                      | **Treatment 2:** cefiderocol (Shionogi & Co., Ltd) | CRE CRPA CRAB | Reserve treatment for hospital and community-acquired bacterial infections in:  
  - adults  
  - children  
  - newborns | 3 million |
| Sepsis       |                      | **Treatment 3:** cefepime-taniborbacatam (Venatorx Pharmaceuticals, Inc.) | CRE CRPA | See above. | 14 million |
| STI          |                      | **Treatment 4:** zoliflodacin (Entasis Therapeutics Limited) | *Neisseria gonorrhoeae* | Oral treatment for uncomplicated gonorrhoea. | 45 million |
| Sepsis or STI|                      | **Treatment 5:** TBD | TBD | TBD | TBD |

*ESBL: extended spectrum beta-lactamases – producing Enterobacteriales; CRE: carbapenem-resistant Enterobacteriaceae; CRPA: carbapenem-resistant *Pseudomonas aeruginosa*; CRAB: carbapenem-resistant *Acinetobacter baumannii*. 

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WHO should formalize a numerical target of “highly-impactful” antibacterial treatments (including innovative products as well as paediatric formulations and combinations of new and existing antibiotics) for the next decade so that governments and philanthropic organizations, with the support of the Global AMR R&D Hub, can compare needed and expected investments to guide their long-term funding.

Governments should close the funding gap for early-stage product development in order to replenish the clinical pipeline with much-needed innovative and “highly-impactful” projects.

Governments should close the funding gap for clinical development, registration, manufacturing, post-approval trials and sustainable access in high-burden LMICs.

Government should implement pull incentives that bring private investors back into antibacterial R&D while ensuring equitable and sustainable access globally.

Provided there are adequate funding and financing mechanisms in place, pharmaceutical companies should align their R&D programs to address unmet needs defined under the WHO Priority Pathogen List, and assure equitable and sustainable access to new and existing antibiotics.
Thank you