Global Antibiotic Research and Development (GARD) Partnership

Developing new antibiotic treatments, promoting responsible use, and ensuring access for all

> 'Antimicrobial resistance threatens the very core of modern medicine and the sustainability of an effective, global public health response to the enduring threat from infectious diseases. Effective antimicrobial drugs are prerequisites for both preventive and curative measures, protecting patients from potentially fatal diseases and ensuring that complex procedures, such as surgery and chemotherapy, can be provided at low risk. Yet systematic misuse and overuse of these drugs in human medicine and food production have put every nation at risk. Few replacement products are in the pipeline. Without harmonized and immediate action on a global scale, the world is heading towards a post-antibiotic era in which common infections could once again kill.'
> ***Global Action Plan on Antimicrobial Resistance*, World Health Organization, 2015**

A critical issue is the failure of current incentive mechanisms to replenish the empty antibiotic R&D pipeline. There is an urgent need for increased investment into R&D. Alternative business models and incentives, including 'delinkage' of the cost of R&D from volume-based sales and price of treatments, that promote responsible use while facilitating equitable access for all, need to be tested.

GARD: Filling critical gaps in R&D

The Global Antibiotic Research and Development (GARD) Partnership is a joint initiative by WHO and DND*i*.

> *GARD's vision is to work in cooperation with the public and private sectors, to develop new antibiotic treatments addressing antimicrobial resistance and to promote their responsible use for optimal conservation, while ensuring equitable access for all, with a focus on global health needs.*

A partnership model for product development based on the experience gained from the field of neglected diseases can provide an important element of the overall strategy for R&D in the field of antibiotics. Such a partnership can test new incentives that also contribute to conservation of and access to new antibiotic treatments. By doing so, it can provide an important alternative to the traditional market-driven pharmaceutical approach, by focusing on products that the pharmaceutical industry will likely not develop for lack of profitability.

Launched in May 2016, GARD is now in its incubation, or start-up phase, hosted by DND*i*. This means that until the end of 2017, GARD will build up its team, establish a legal entity, and set out its long-term strategy and roadmap. In addition, GARD aims to have at least two projects that address urgent global health needs ready for implementation by the end of 2016, and two more by the end of 2017.

How will GARD work?
GARD will work closely with all stakeholders in the field of antibiotic research and development (R&D) – including pharmaceutical and biotechnology companies, startups, other product development partnerships, academia, civil society, and health authorities – from countries of all income levels – to develop new antibiotic treatments.
It will:

- address global public health and specific needs of low- and middle-income countries;
- target products that industry will likely not develop due to lack of profitability or other reasons;
- pilot the use of alternative incentive models delinking cost of R&D from volume-based sales and prices of antibiotics, which support conservation of and access to new antibiotics; and
- ensure that new antibiotics developed by GARD are affordable to all in need.

WHO and DND*i* collaborate to incubate GARD
The Drugs for Neglected Diseases initiative, a not-for-profit research and development organization that applies and alternative business model to traditional R&D approaches, built a new business plan in 2015. The latter paved the way to a more flexible, dynamic portfolio approach, integrating various operating models to better respond to patient needs. DND*i*'s consultations with its founding partners and key global public health actors identified antimicrobial resistance as a key area of need. Among the operating models was the possibility for DND*i* to incubate a new initiative – which would ultimately become an independent entity – much in the way that DND*i* itself was incubated by Médecins Sans Frontières in 2003.

This coincided with a process ongoing at WHO: The Sixty-eighth World Health Assembly in 2015 adopted the Global Action Plan on Antimicrobial Resistance (GAP-AMR), requiring the WHO Secretariat to propose options for the establishment of new partnerships to identify priorities for new treatments, diagnostics, and vaccines to fight resistant pathogens; to act as the vehicle for securing and managing investment in new medicines, diagnostics, vaccines and other interventions; and to establish open collaborative models of research and development facilitating access to the outcomes of such research.

Respective roles of DND*i* and WHO in incubating GARD
Hosted by DND*i*, the GARD team is responsible for developing the GARD business plan; fundraising; building the scientific strategy; setting up a scientific working group and steering committee; preparing for the creation of an independent entity; and building a product pipeline. GARD's governance is *de facto* embedded into DND*i*'s governance structure during this start-up phase. WHO will provide support in priority setting, stewardship, and access; report back to its Member States; secure close collaboration with the AMR Secretariat, relevant WHO departments, the Essential Medicines List team, and the Global Health R&D Observatory; and provide other technical input where needed.

Seed funding for GARD incubation secured
At the time of its launch on 24 May 2016, GARD has secured seed funding commitments from the Federal Ministry of Health of Germany, the Netherlands' Ministry of Health Welfare and Sports, the South African Medical Research Council, and the United Kingdom Department for International Development as well as from Médecins Sans Frontières, totalling over EUR 2 million of the projected EUR 3 million required for the incubation phase.

www.dndi.org/GARD