

**Submission to US Department of Health and Human Services request for information on the National Action Plan for Combatting Antibiotic Resistant Bacteria 2020-2025**

*Submitted online on January 7, 2019.*

**Goal 4: Accelerate basic and applied research and development for new antibiotics and other therapeutics, including vaccines.**

**Response 4** (*Character limit = 500 words/250 per priority*)

Members of the Global Health Technologies Coalition work around the world to advance solutions to accelerate the development of new health technologies to address neglected global diseases and health conditions, including antimicrobial resistance (AMR), and stand ready to collaborate to further the objectives of the next National Action Plan for Combating Antimicrobial Resistance.

The research and development of new tools must remain a critical piece of the National Action Plan. The US government's investment in drugs, diagnostics, and vaccines to counter drug resistant pathogens prevalent in low- and middle-income countries (LMICs) is key to improving global health and ultimately protecting Americans. Tuberculosis (TB), recognized by the CDC as a serious threat level pathogen, is the leading cause of death globally from AMR, responsible for one-third of deaths associated with drug resistance. WHO estimates that almost 600,000 people developed resistance to at least one of the key drugs from the current treatment regimen for TB in 2017, with 457,560 developing multi-drug resistant (MDR) TB – of whom 38,892 developed extensively drug resistant (XDR) TB. Treating drug-resistant TB requires long, toxic, expensive, complex regimens with limited effectiveness. New drug regimens are urgently needed.

The limited commercial incentives for product development for diseases of poverty hampers progress towards new TB drug regimens and a universally effective TB vaccine. The US government has successfully addressed similar market limitations for other biomedical challenges through the Biomedical Advanced Research and Development Authority (BARDA). One priority for the National Action Plan 2020-2025 should be adding drug resistant TB to BARDA's mandate as part of the CARB initiative and/or its broader emerging infectious diseases portfolio and setting specific targets for BARDA's contributions to TB product development over the next five years.

In addition to TB, the next National Action Plan should prioritize and set specific targets for the development of products that are affordable, accessible, and appropriate to address drug resistant pathogens more broadly in low-resource settings. The creation and expansion of incentive mechanisms to attract product development partners, including private industry, to product development activities that address the full extent of the global burden of AMR are critical to promoting a healthier world and safer America.

**Domestic or International:**

- Domestic
- International

**Relates to:**

- Human health
- Animal health
- Environment

**Goal 5: Improve international collaboration and capacities for antibiotic resistance prevention, surveillance, control and antibiotic research and development.**

**Response 5** (*Character limit = 500 words/250 per priority*)

Addressing antimicrobial resistance to protect Americans requires a global response and strong international engagement. The next National Action Plan should continue to prioritize the establishment, promotion and expansion of international collaborations and public-private product development partnerships to spur the development of new products to counter antimicrobial resistance in low and middle-income countries (LMICs), including therapeutics, vaccines and diagnostics, and should include specific numerical targets to advance this goal.

Efforts to strengthen regulatory and supply chain systems in low and middle-income countries to assure the quality, safety, efficacy and appropriate access to antibiotics must continue to be a priority. USAID and other federal agencies should prioritize facilitating improvements in country systems in at least ten additional LMICs from 2020-2025 to enhance access to and appropriate use of safe, effective, essential antibiotics through improved medicines, regulatory capacities, secure supply chains and quality assurance systems. US leadership to foster country engagement and partnership is essential.

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