

What does FDA do for global health R&D?

The US Food and Drug Administration (FDA) regulates the safety and efficacy of drugs, vaccines, and other medical products marketed in the United States, which can include products also designed for use overseas. The FDA also works with international regulators in low- and middle-income countries (LMICs) to strengthen their regulatory capacity and provide technical assistance.

Why is FDA's role in global health R&D important?

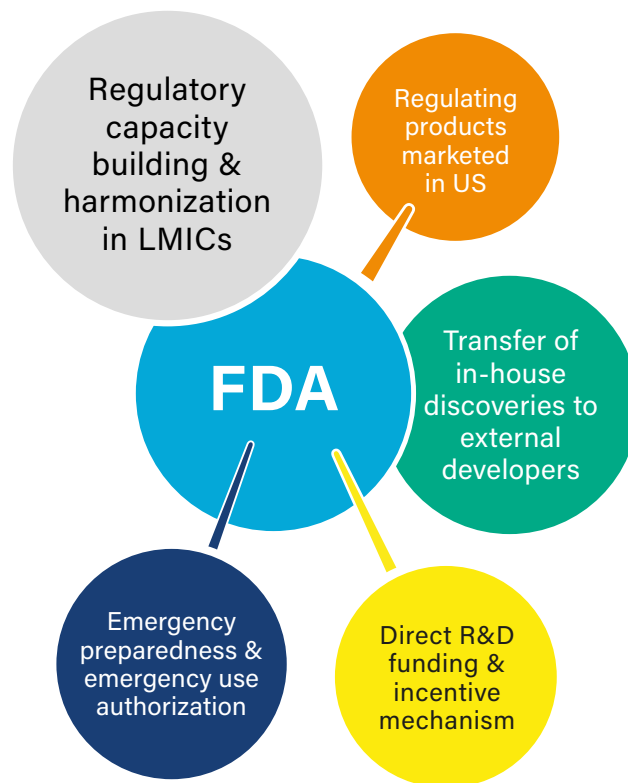
FDA's approval of a product serves as a "gold standard" that can expedite regulatory review in LMICs. This effect, combined with the agency's work in regulatory capacity building, helps ensure new global health technologies are safe, effective, and accessible in low-resource settings.

Impact of Investment

The FDA has approved more than **50 drugs**, vaccines, and diagnostics for neglected diseases.

The FDA has **150** formal arrangements for information sharing and technical assistance with regulatory authorities in **36** countries.

Contributions to Global Health R&D



FDA R&D success stories: Saving lives, saving money



CAPACITY BUILDING

Development of partnerships to **strengthen regulatory capacity in low- and middle-income countries**, including collaborations with the World Health Organization (WHO) African Vaccine Regulatory Forum and the WHO Developing Country Vaccine Regulators Network to share expertise and provide training and mentoring.



MENINGITIS

Development of critical technology used in **low-cost meningitis A vaccine**, which has **prevented 378,000 deaths** and **saved 63,000 children from lifelong disability** in just seven years, and is predicted to have **saved US\$9 billion** in treatment costs by 2020.



HIV/AIDS

Creation of a **"tentative approval" process** allowing the President's Emergency Plan for AIDS Relief (PEPFAR) to purchase generic **antiretroviral (ARV) drugs** for use outside the United States. Through the program, the FDA has approved more than 190 ARVs, which have supported **treatment for more than 3.9 million people** worldwide.



EMERGING DISEASES

Granted Emergency Use Authorization to **27 diagnostic tests for Zika and Ebola**, allowing promising tools not yet approved to be used during these crises.



NTDs

Release of guidance documents to aid organizations in developing **drugs for neglected tropical diseases (NTDs)** and issuance of **five priority review vouchers (PRVs)** as part of the NTD PRV program intended to stimulate private-sector investment in NTD R&D.



TB

Use of an accelerated approval pathway to speed review and approval of the first **new tuberculosis (TB) drug** from a novel class to be approved in over 40 years.