

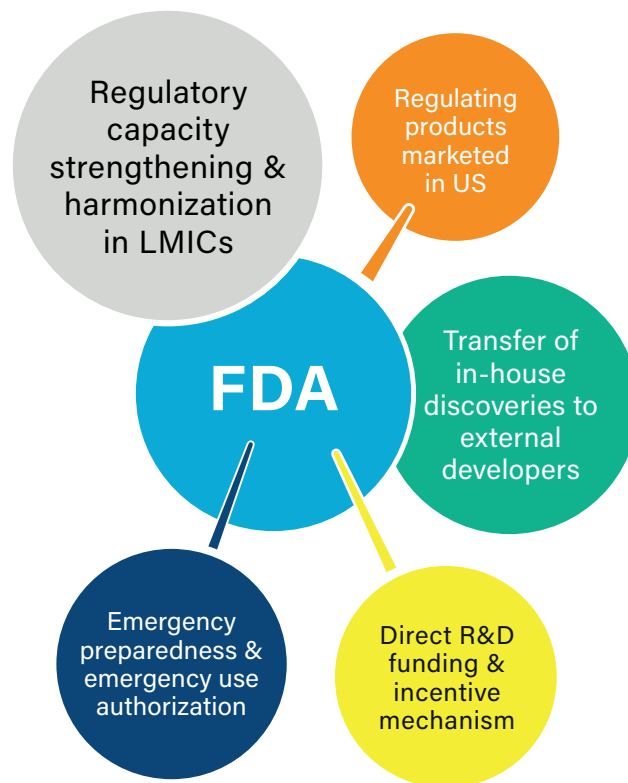
What does FDA do for global health R&D?

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 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-strengthening, helps ensure new global health technologies are safe, effective, and accessible in low-resource settings.

Contributions to global health R&D



Ensuring safe & effective products

The FDA has approved more than **75 drugs, vaccines, and diagnostics** for neglected diseases.

The FDA has **201 formal arrangements** for information sharing and technical assistance with regulatory authorities in **54 countries**.

IMPACT OF INVESTMENT



CAPACITY STRENGTHENING

Development of partnerships to **strengthen regulatory capacity in LMICs**, 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.



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 200 ARVs, which have helped support **treatment for more than 20 million people** worldwide.



HEALTH EMERGENCIES

Granted emergency use authorization for **more than 400 medical products for COVID-19**, **18 diagnostics for Zika**, and **11 diagnostics for Ebola**, facilitating their use during these crises.



MENINGITIS

Development of critical technology used in a **low-cost meningitis A vaccine**, which as of 2020, has been delivered to more than **340 million people in 24 countries**, virtually eliminating meningitis A wherever it has been used.



NTDs

Release of guidance documents to aid organizations in developing **drugs for neglected tropical diseases (NTDs)** and issuance of **12 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 **two new drugs to treat drug-resistant tuberculosis (TB)**.