Global Health R&D at FDA

GHTC global health technologies coalition

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. FDA also works with the World Health Organization (WHO) and international regulators in low- and middle-income countries (LMICs) to strengthen regulatory capacity and provide technical assistance.

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

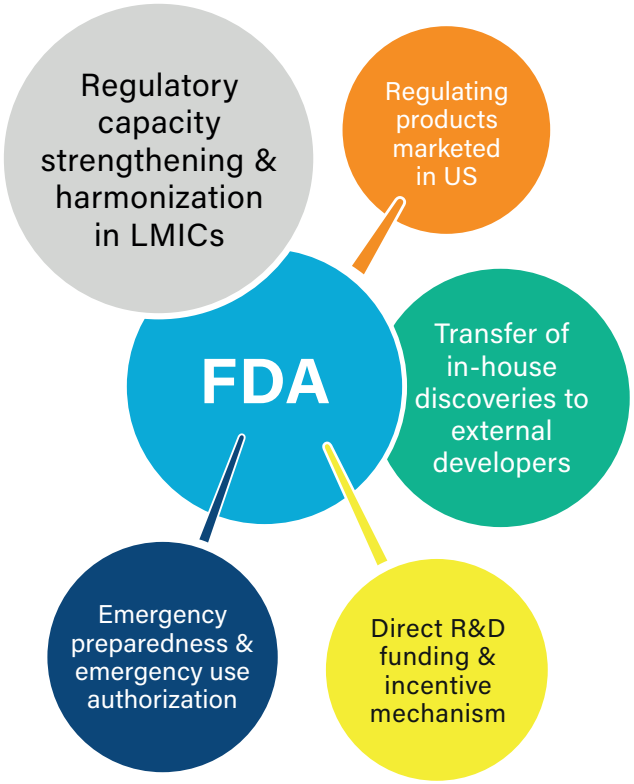
FDA approval of a product serves as a "gold standard" that can expedite regulatory review in LMICs. This effect, combined with the agency's work in regulatory capacity-strengthening, helps ensure new global health technologies are safe, effective, and accessible in low-resource settings.

Ensuring safe & effective products

FDA has approved more than **110 drugs, vaccines, and diagnostics** for neglected and emerging diseases.

FDA has **208 formal arrangements** for information sharing and technical assistance with regulatory authorities in **55 countries**.

Contributions to global health R&D



R&D SUCCESS STORIES

CAPACITY-STRENGTHENING

Development of partnerships to **strengthen regulatory capacity in LMICs**, including collaborations with the WHO African Vaccine Regulatory Forum to share expertise and provide training and mentoring.

HIV/AIDS

Creation of a **"tentative approval"** process to certify **antiretroviral (ARV)** drugs that the President's Emergency Plan for AIDS Relief, or PEPFAR, purchases for use outside the United States. Through this program and standard review, FDA has approved more than 250 ARVs, which have helped support **treatment for more than 20.5 million people worldwide** via PEPFAR.

HEALTH EMERGENCIES

Granted emergency use authorization for **more than 400 medical products for COVID-19, 9 products for mpox, 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 **14 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).