USAID MEDICINES, TECHNOLOGIES, AND PHARMACEUTICAL SERVICES (MTaPS) PROGRAM

Improved Access. Improved Services. Better Health Outcomes.

Photo by Warren Zelman

MTaPS objectives

1. Pharmaceutical-sector governance strengthened
2. Institutional and human resource capacity for pharmaceutical management and services increased, including regulation of medical products
3. Availability and use of pharmaceutical information for decision making increased and global learning agenda advanced
4. Pharmaceutical-sector financing, including resource allocation and use, optimized
5. Pharmaceutical services, including product availability and patient-centered care, to achieve health outcomes improved

The MTaPS Program is from the American People through USAID

Based on its decades of expertise in strengthening health systems to save lives and improve the health of people in low- and middle-income countries, USAID supports better governance and integrated, innovative, and sustainable strategies to strengthen pharmaceutical systems.

Funded by the US Agency for International Development and led by Management Sciences for Health (MSH), the goal of the five-year USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program (2018–2023) is to help low- and middle-income countries strengthen their pharmaceutical systems to ensure sustainable access to and appropriate use of safe, effective, quality-assured, and affordable essential medicines and pharmaceutical services.

USAID FROM THE AMERICAN PEOPLE

SUPPORTING PHARMACEUTICAL REGULATORY SYSTEMS

Strong pharmaceutical regulatory systems are essential to ensure sustainable access to and appropriate use of safe, effective, quality-assured, and affordable essential medicines and pharmaceutical services that contribute to better health care delivery systems.

National medicines regulatory authorities (NMRAs) in low- and middle-income countries (LMICs) face significant challenges in controlling the quality, safety, and efficacy of medical products circulating on their markets or passing through their territories. In sub-Saharan African countries, for example, an assessment of 26 NMRAs published by the World Health Organization (WHO) in 2010 found that although countries had legal provisions for most essential aspects of medicine control, capacity was inadequate and regulatory measures did not form a coherent control system.[1]

Weaknesses in pharmaceutical regulatory systems contribute to limited access to quality-assured, safe, and efficacious life-saving essential medicines, including those for malaria; HIV/AIDS; and reproductive, maternal, and childhood diseases, and to the disruption of health service delivery, thereby preventing achievement of better health outcomes.

USAID MTaPS supports LMICs to improve their pharmaceutical regulatory systems, including pharmacovigilance (PV) systems, to deliver safe, effective, and quality-assured medicines by:

- Strengthening regulatory capacity and pharmaceutical-sector governance to protect the public from substandard and falsified products
- Promoting transparency and accountability through appropriate laws, regulations, policies, and standard operating procedures
- Improving human and institutional capacity to manage pharmaceutical regulatory systems and services, including protecting patient safety and slowing the emergence and spread of antimicrobial resistance

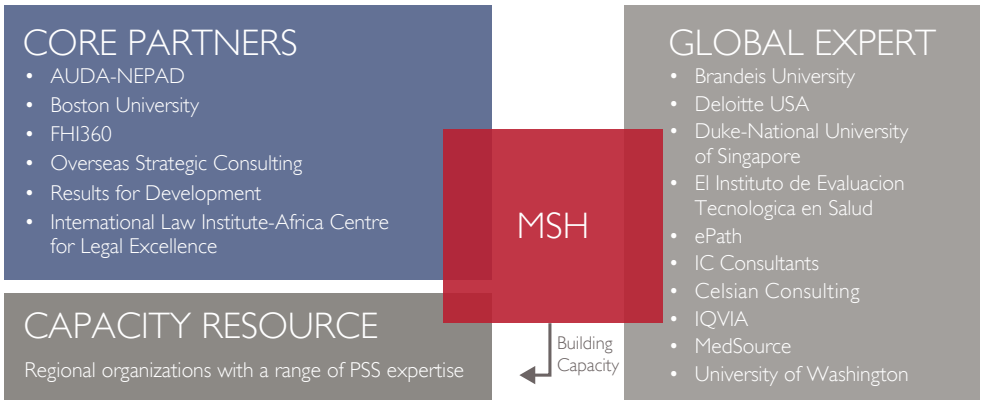
[1] WHO (2010). Assessment of medicines regulatory systems in sub-Saharan African countries. Available at: https://www.who.int/healthsystems/Assessment26African_countries.pdf?ua=1

MTaPS helps countries:

- Adopt model pharmaceutical legislation, policies, guidelines, and norms or update existing tools that promote equitable and sustainable access to safe and efficacious medicines of assured quality
- Establish mechanisms to ensure oversight and enforcement of policies, laws, and regulations, including the development of country-specific strategies for enforcement and compliance and collaboration with national, regional, and international authorities
- As an entry point, support NMRAs' strategic planning for regulatory system strengthening with a focus on product registration
- Develop NMRAs' institutional capacity for on-the-job training, knowledge sharing, and adaptation of model tools (SOPs and guidelines) and help establish certification programs to encourage continued capacity development and resource optimization
- Support strengthening/developing pharmaceutical regulatory professionals and preservice programs in collaboration with MTaPS partners Regional Centres of Regulatory Excellence in Africa and the Centre of Regulatory Excellence in Asia
- Support coordination and advocacy efforts for regional harmonization through regional economic communities and platforms like the African Medicines Regulatory Harmonization initiative
- Support regional coordination of assessment, technical assistance, and M&E for regulatory systems strengthening in collaboration with stakeholders and donors (e.g., WHO, World Bank, Bill & Melinda Gates Foundation)
- Support interoperability of regulatory data among countries through data requirement analysis, creation of data exchange systems, and use of information solutions such as Pharmadex for medicines registration; PViMS for active surveillance of and spontaneous reporting on medicine safety; and WHO GBT for assessment of regulatory systems
- Validate the effectiveness of innovative community point-of-sale screening of substandard and falsified medicines to improve patient safety
- Improve PV systems
- Design active surveillance systems for new medicines to support the use of high-risk and novel technologies
- Support behavior change interventions for providers and patients to increase voluntary reporting of adverse drug events

The MTaPS Consortium

Led by Management Sciences for Health (MSH), the MTaPS consortium comprises core partners, global experts, and capacity resource partners. Core partners and global experts are listed below. Capacity resource partners include local organizations with regional or country-based knowledge, technical expertise, and networks (African Health Economics and Policy Association, African Collaborating Centre for Pharmacovigilance and Surveillance, Ecumenical Pharmaceutical Network, Kilimanjaro School of Pharmacy, Muhimbili University, Pharmaceutical Systems Africa, U3 SystemsWork, and the University of Ibadan) and other partners (Columbus Consulting, Empower Swiss, and Softworks).



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