USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program

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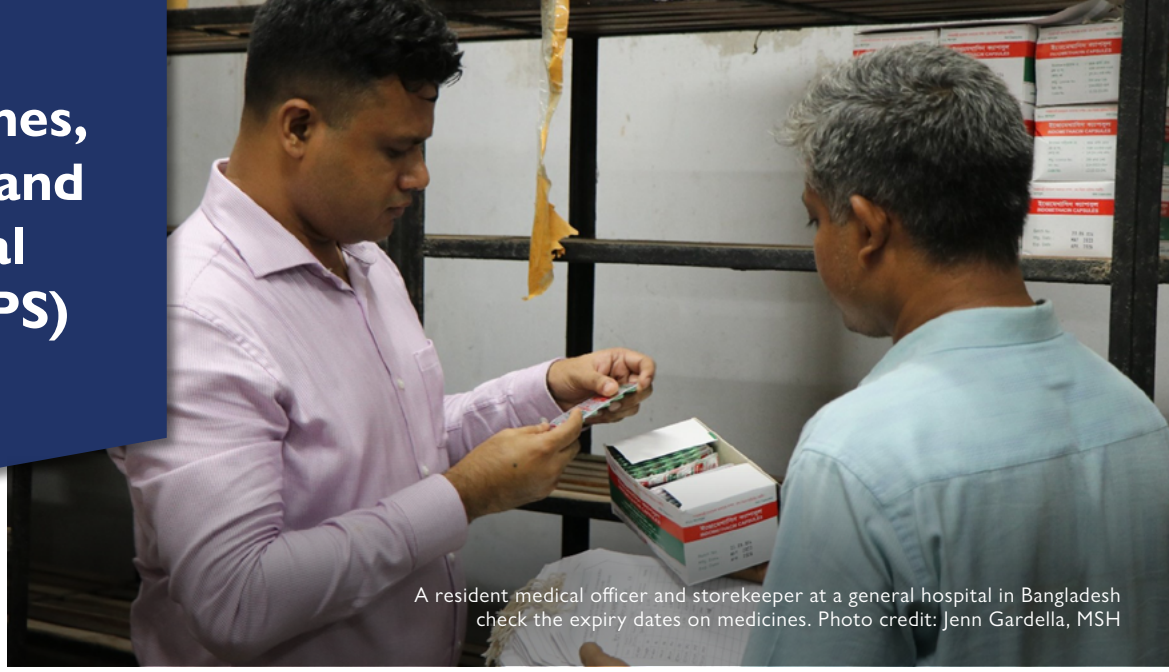

A resident medical officer and storekeeper at a general hospital in Bangladesh check the expiry dates on medicines. Photo credit: Jenn Gardella, MSH

MTaPS SUMMARY REPORT
ASIA BUREAU (2019–2025)

About USAID MTaPS

The US Agency for International Development (USAID) Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program (2018–2025) enables low- and middle-income countries to strengthen their pharmaceutical systems, which are essential to establishing higher-performing health systems and achieving better health outcomes. The program is implemented by a consortium of global and local partners, led by Management Sciences for Health (MSH), a global health nonprofit.

Learn more at
https://www.mtapsprogram.org/

INTRODUCTION

The USAID MTaPS program enables low and middle-income countries (LMICs) to strengthen their pharmaceutical systems, which are critical for ensuring access to and appropriate use of safe, effective, quality-assured, affordable medicines, vaccines, health technologies and products, and related pharmaceutical services to improve health. MTaPS' objectives are to (1) strengthen pharmaceutical-sector governance; (2) increase institutional and human resource capacity for pharmaceutical management and services, including regulation of medical products; (3) increase availability and use of pharmaceutical information for decision making and advance the global learning agenda; (4) optimize pharmaceutical-sector financing, including resource allocation and use; and (5) improve pharmaceutical services, including product availability and patient-centered care, to achieve desired health outcomes.

MTaPS employs a pharmaceutical system–strengthening (PSS) approach to identify and implement strategies and actions that achieve coordinated and sustainable improvements of a pharmaceutical system to make it more responsive and resilient for achieving better health outcomes. The MTaPS approach emphasizes locally led development, country ownership, and self-reliance to support countries on the pathway to sustainability.

From 2019 to 2025, funded by USAID's Asia Bureau, MTaPS advanced pharmaceutical management systems within Asia by strengthening capacity to institutionalize transparent and evidence-based decision-making, use robust information to define and cost pharmaceutical coverage, and improve medicine regulatory capacity and pharmaceutical-sector governance.

USAID
FROM THE AMERICAN PEOPLE

CHALLENGES

- Ill-defined benefits packages that allocate resources to unnecessary or ineffective medical technologies
- Countries' lack of capacity to cost pharmaceutical benefits packages or track expenditures
- Weak governance and regulatory capacity and processes at most of the region's NRAs
- NRAs' inadequate safety monitoring and pharmacovigilance
- Lack of local-level capacity to effectively conduct complex, decentralized procurement processes

PARTNERS

- Association of Southeast Asia Nations (ASEAN)
- HTAsiaLink
- International Decision Support Initiative
- Indonesian Ministry of Health
- IQVIA Philippines
- Philippines
  - Department of Health (DOH)
  - DOH–Pharmacy Division
  - DOH–Procurement Services (PS)
  - DOH–Disease Prevention and Control Bureau
  - DOH–retained hospitals
  - Government Procurement Policy Board (GPPB)
  - Local Government Units (LGUs)
- Results for Development (R4D)
- Southeast Asia Regulatory Network (SEARN)
- USAID Promoting Quality of Medicines Plus (PQM+)
- Universitas Gadjah Mada
- Universitas Indonesia
- U3 SystemsWork
- WHO
- WHO South-East Asia Regional Office (SEARO)

CONTEXT

In many countries in Asia, poor pharmaceutical-sector governance and weak regulatory and procurement capacity and processes can diminish access to high-quality, safe, and effective medical products; drive up medicine prices; and waste scarce resources. Additionally, these weaknesses can harm individual patients, for example, by allowing substandard or falsified products to enter markets. Similarly, inadequate monitoring of new medicines can result in missed critical evidence on adverse events among patients. Because pharmaceutical systems are complex and involve expensive products, they are susceptible to mismanagement and corruption.[1,2] In addition, countries without robust systems for setting spending priorities often develop ill-defined benefits packages that allocate resources to unnecessary or ineffective medical technologies.

Policymakers need to be able to cost a pharmaceutical benefits packages to understand how much public and private payers will spend on a given pharmaceutical coverage scenario and how much spending will change under new or revised coverage schemes. However, many Asian countries lack the expertise to conduct such costing. Furthermore, as countries transition from donor-supported, centralized procurement to locally funded and decentralized procurements, they lack economies of scale and are unable to effectively complete long procurement processes. While Asia has made substantial progress in advancing medical product regulations, some countries have limited resources for regulating medicines, and gaps remain in the institutional and technical capacity of national regulatory authorities (NRAs).

STRATEGIC APPROACH

To increase Asian countries' ability to institutionalize evidence-based decision making, regulate the pharmaceutical sector more effectively, reduce conflict of interest (COI), and strengthen strategic procurement initiatives, MTaPS collaborated with public- and private-sector stakeholders at both the regional and country levels. Specifically, countries used health technology assessment (HTA) and pharmaceutical expenditure (PE) tracking to prioritize their health investments. A comprehensive road map and other resources to guide countries' HTA processes complemented coordination with regional actors, such as HTAsiaLink—a regional network for HTA research and evidence-based policy—to strengthen capacity and sustain continuous learning as HTA gains traction. Likewise, MTaPS reviewed pricing policies and coverage across the region and developed guidance for using PE tracking to define and cost pharmaceutical benefits packages.

Following a systems strengthening approach, MTaPS worked with countries and regional entities to build NRAs' organizational capacities to align with the World Health Organization (WHO) Global Benchmarking Tool indicators. Activities with ASEAN and SEARN member states focused on streamlining product registration—from enhancing regional collaboration on data sharing, convergence, and harmonized standards to reviewing dossiers for biologics and vaccines. Avoiding COI between decision makers and the private sector is a major step toward creating strong sectoral governance structures. MTaPS assessed the region's COI landscape and collaborated with WHO to create an e-Learning course and convene an international group to develop a manual for preventing and managing COI; later, officials from 12 countries shared their experiences with COI and the application of the manual.

Finally, MTaPS worked with health procurement officials in the Philippines to examine policies and operational frameworks and to identify mechanisms to increase strategic, transparent procurements such as pooled procurement.

KEY MILESTONES

2020
- *A Roadmap for Systemic Priority Setting and Health Technology Assessment (HTA)* guidelines published
- Mapping of regional stakeholder involved in strengthening regulatory systems in Asia completed

2021
- Workshop held for SEARN member countries on vaccine dossier evaluation and registration
- Good Manufacturing Practices online course for pharmaceutical manufacturers in India developed

2022
- Legal analysis of laws, policies, and regulations affecting health product procurement in the Philippines conducted
- Gaps in pharmaceutical committee COI policies in SEARO region analyzed and COI e-Learning course launched through OpenWHO

2023
- Guidelines, surveys, and hands-on exercises developed to standardize PE tracking in the Asia region
- Demand for HTA hub in Asia characterized by 25 global HTA leaders through literature reviews, surveys, and informant interviews

2024
- *The Clinical Equipment and Devices HTA Methods Guide* published and officially recognized by the Philippines government
- Factors affecting DOH's procurement successes and failures in the Philippines assessed and technical advisory with recommendations drafted

KEY RESULTS

Strengthening evidence-based prioritization through HTA

- *A Roadmap for Systematic Priority Setting and Health Technology Assessment (HTA)* developed with contributions from global experts that will support LMICs' efforts to build strong HTA programs that transparently guide decision making.
- The growing demand for HTA capacity building and systems development in Asia was assessed, and gaps in developing regional HTA capacity characterized through document analysis, surveys, and interviews that will guide future efforts.
- *Asia HTA Hub Assessment Report* identified and highlighted priorities such as integrating capacity-development plans and enhancing political support for HTA systems. The report described successful models for collaboration with HTAsiaLink to strengthen the regional hub that was subsequently implemented.
- *Clinical Equipment and Devices HTA Methods Guide* published in partnership with the HTA Division and the Department of Science and Technology in the Philippines to provide a resource on how to assess and adopt medical devices. The Philippines adopted the guide and now has specific guidelines to assess and include critical medical devices in the country.
- A two-country workshop between Indonesia and the Philippines, co-led between MTaPS and the Philippines Department of Science and Technology, improved each country's ability to evaluate medical devices and fostered dialog and learning on conducting high-quality HTA.

Improving ability to cost pharmaceutical benefits coverage

- The ability of 46 representatives (14 female) from Kyrgyzstan, Bangladesh, Nepal, and the Philippines to define and cost evidence-based pharmaceutical benefits programs enhanced by using the OneHealth Tool, which provides a framework to plan and budget health program components and determine impact.
- 14 staff (2 female) from Bangladesh's Health Economics Unit and other government and partner agencies capacitated to use the OneHealth Tool to cost and analyze the impact of national social health protection interventions. Bangladesh has subsequently applied the OneHealth Tool for its universal health coverage costing.

46 representatives from Asia increased their capacity to define and cost evidence-based pharmaceutical benefit programs using the OneHealth Tool.

- Tools and guidance documents produced that provide resources for countries in the region to define and cost pharmaceutical benefits packages as part of the effort to achieve UHC:
    1. Review of pricing policies and price lists available in Asia regional countries
    2. Pharmaceutical benefits and benefits packages in Asia: A cross-country mapping of coverage arrangements
    3. Review of existing tools for estimating financial outlays for a defined pharmaceutical benefits package - Part 1
    4. Guidance for estimating expected financial outlays for a defined pharmaceutical benefits package – Part 2
    5. Key steps for defining pharmaceutical benefits packages

Building harmonized, efficient regulatory systems

In ASEAN member states,

15 **professionals** equipped with skills to carry out Good Review Practices for product dossiers and to adopt WHO collaborative procedures and

25 **professionals** trained as trainers to support the evaluation of biologicals, including vaccines.

- 12 regional harmonization events (meetings, workshops, conferences) organized that enhanced regulatory maturity of MTaPS-supported NRAs and supported regional collaboration, convergence, and harmonization
- 15 participants (9 female) from ASEAN member states equipped with skills to carry out Good Review Practices for health product dossiers and adopt WHO collaborative procedures, enabling them to streamline and improve NRAs' quality-of-health product registration procedures.
- A pool of 25 trainers (19 female) from ASEAN member states trained as trainers to promote knowledge exchange and convergence of technical standards, strengthen the marketing authorization function by improving evaluation proficiency in vaccines, and increase access to biologics, including COVID-19 vaccines, of assured quality, safety and efficacy/immunogenicity.
- Capacity of 19 participants from Bangladesh and Nepal developed on convergence of technical standards and guidelines. A random sampling of post-training results showed a 20% increase in knowledge (highlighting improved understanding of the need for convergence of technical standards and guidelines to improve reliability and efficiency of their countries' medicine registration processes).
- 20 regulatory officials (9 female) from Bangladesh and Nepal instructed on the procedures to assess dossiers to expedite the registration of COVID-19 vaccines to improve their countries' response to the COVID-19 pandemic.
- Competency mapping of regulatory workforces in Bangladesh, Nepal, and the Philippines completed, and targeted training plans developed for regulatory staff to carry out their roles more proficiently, contributing to a more mature, robust, and stable regulatory system.
- Competency needs in regulatory functions identified and a capacity-strengthening strategy and action plans for SEARN member countries developed that will increase country-level capacity and contribute to NRA regulatory maturity.

Strengthening pharmaceutical-sector governance

1,400 **learners** completed the COI e-Learning course on the OpenWHO platform from October 2023 to March 2024.

- COI landscape in 10 countries characterized and key gaps identified, which will guide efforts to strengthen pharmaceutical-sector governance in Asia.
- International working group established that created a manual for preventing and managing COI (*Managing conflicts of interest, a how-to guide for public pharmaceutical-sector committees in low- and middle-income countries*); WHO approved the manual and published it on their website, where it was downloaded 520 times from October 2023 to March 2024.
- Joint Learning Network was leveraged to engage 36 government officials from 12 countries in a learning collaborative for approximately 3 months. During the program, participants were oriented to the COI WHO manual (developed with MTaPS) and asked to apply the COI principles to workplace situations under their direct responsibility, within their pharmaceutical system.
- COI e-Learning course developed on the OpenWHO platform in collaboration with WHO; 1,400 learners completed the course from October 2023 to March 2024. The Malaysia Ministry of Health (MOH) adopted the course as an onboarding tool for all pharmaceutical inspectors.

Strengthening strategic pharmaceutical procurement in the Philippines

- Insights into current procurement laws, policies, and regulations in the Philippines documented in a report that identifies constraints, opportunities, and recommendations to implement pooled procurement.
- A policy for introducing pooled procurement at LGUs and DOH hospitals drafted by DOH-PS based on legal analysis and above recommendations.
- Selected LGUs and DOH hospitals assessed to understand their capacity and willingness to participate in the pilot pooled procurement program to determine their readiness to test the new policy using specific health products.
- A model pooled procurement implementation plan for health products developed that the DOH and other stakeholders can easily adapt and use to quickly pilot pooled procurement at LGUs and DOH hospitals once policy is approved.

PEER-REVIEWED PUBLICATIONS

- Disclosure, transparency, and accountability: a qualitative survey of public sector pharmaceutical committee conflict of interest policies in the World Health Organization South-East Asia Region
- Assessing progression of health technology assessment implementation in Asia: a balanced scorecard for cross comparison of selected countries in Asia
- Exploring facilitators and barriers to introducing health technology assessment: a systematic review

PATHWAY TO SUSTAINABILITY

MTaPS provides technical assistance in establishing strategic direction and development of critical capacities on a pathway to sustainable and resilient pharmaceutical systems. Through its activities under the Asia Bureau portfolio, MTaPS advanced pharmaceutical management systems in the region by strengthening the capacity to institutionalize transparent and evidence-based decision making, use robust information to define and cost pharmaceutical coverage, and improve medicine regulatory capacity and pharmaceutical-sector governance.

- The diverse utility of *A Roadmap for Systemic Priority Setting and Health Technology Assessment* has been proven in multiple countries; for example, the Indonesia MOH used the road map to emphasize real-world evidence, and the Philippines HTA Division used it to guide clinical evaluation of devices. It was also used in Ethiopia and Kenya—highlighting the road map's flexibility and relevance in providing ongoing HTA support in other LMICs.
- *The Asia Hub Report* identified the feasibility of establishing a regional hub for HTA capacity development to guide future strategies and collaboration with local organizations, such as the Health Intervention and Technology Assessment Program and ASEAN.
- A pool of assessors from the region are equipped with skills to better evaluate medicine dossiers, including for complex products such as vaccines and biologics; they are capacitated to mentor other assessors and expand regulatory resources in the Asia region.
- A WHO-endorsed COI manual and e-Learning course are in use globally.
- The DOH-PS in the Philippines used the legal analysis of procurement practices and recommendations that MTaPS helped develop to draft a pooled procurement policy for health facilities/LGUs.
- MTaPS collaborated with IQVIA Philippines to guide product and health facility selection for the pooled procurement pilot study; IQVIA can potentially continue supporting the DOH after MTaPS. MTaPS handed over a package of procurement resources to the DOH and implementing partners to ensure the ready availability of all the resources developed so far. The resources can be used by the DOH and partners to organize and conduct a pilot study on the feasibility of LGUs and DOH hospitals using pooled procurement, as well as to guide other decision-making and best practices.

FEATURED RESOURCES

- A Roadmap for Systemic Priority Setting and Health Technology Assessment (HTA): A Practical Guide for Policy Action in Low- And Middle-Income Countries
- Asia HTA Hub Assessment Report
- Philippine HTA Methods Guide Clinical Equipment and Devices (CEDs)
- Managing conflicts of interest, a how-to guide for public pharmaceutical-sector committees in low- and middle-income countries
- Managing Conflict of Interest in National Pharmaceutical Systems e-Learning course
- Conflict of interest management policies and practices in the public pharmaceutical sector in the WHO South-East Asia Region
- Managing Conflicts of Interest in Public Pharmaceutical Committees
- Pharmaceutical Benefits and Benefits Packages in Asia: A Cross-Country Mapping of Coverage Arrangements
- Regulatory Workforce Competency Mapping for National Regulatory Authorities in the Asia Region
- Strengthening Medical Products Registration in the Asia Region
- Using the OneHealth Tool to Allocate Pharmaceuticals Budgets in the Asia Region

RECOMMENDATIONS

- To enhance work sharing, trust, and knowledge exchange, regional regulatory networks, such as the ASEAN pharmaceutical product working group and SEARN, can support twinning field visits between NRAs with limited resources and those with more mature regulatory systems and facilitate joint marketing authorization assessment sessions for key medical products.
- Regional bodies, networks of local organizations, and country health agencies to continue strengthening local HTA capabilities through training and workshops and formalize HTA practices by establishing permanent bodies to oversee policy implementation.
- MOHs and national HTA agencies to integrate tools and methodologies for evaluating health care interventions for systematic priority setting in health care budgeting. This includes integrating real-world evidence into HTA processes and enhancing decision making to meet UHC goals.
- NRAs to use competency mapping findings to develop and implement regulatory staff capacity-building plans. This will enable individuals to grow their skills and knowledge to help the organization ensure safe, quality, and efficacious products and encourage a uniform regulatory approach in the region.
- National pharmaceutical-sector decision-making bodies to use the MTaPS/WHO COI manual and course on OpenWHO platform to advocate for the systematic inclusion of COI approaches in committees within national regulatory, pharmaceutical, and supply chain departments and authorities, and incorporate COI education into health professional pre-service and in-service courses.
- Ethical oversight departments within the ministry of health or public service to provide a safer environment for whistle-blowers who report COI risks and effectively implement legislation that protects them.
- WHO and the Health Economics Unit, the Directorate General of Drug Administration, and the National Institute of Neurosciences & Hospital in Bangladesh to hold seminars and workshops on using PE for evidence-based policy to strengthen capacity and promote its benefits to policymakers and stakeholders.
- The Health Economics Unit in Bangladesh to develop a strategy to institutionalize PE that will guide the administration and coordination of PE activities and ensure that the institutions that collect and process PE data work together to understand and analyze them.
- To advance strategic procurement in the Philippines:
  - DOH and GPPB to further review the legal analysis to develop administrative orders and policies to strengthen strategic procurement initiatives at all levels.
  - DOH-PS, partners, and LGUs/hospitals to follow up on the GPPB's approval of the pooled procurement policy by conducting the pilot study to generate evidence on its potential benefits and wider applications.
  - DOH-PS, partners, and LGUs/hospitals to use the pooled procurement evidence and generic pilot implementation plan to advance the country's strategic procurement agenda.

ASSESSING HTA PROGRESS IN ASIAN COUNTRIES USING A BALANCED SCORECARD

MTaPS Asia Bureau assessed Asian countries' comparative progress on adopting HTA using a scorecard. The scorecard offered a pragmatic framework to evaluate the state of HTA implementation and identify potential weaknesses hindering its progress. A scoring system on a scale of 1 to 5 measured HTA progress in China, India, Indonesia, Malaysia, Philippines, South Korea, Taiwan, Thailand, and Vietnam. A key lesson to advance HTA is to facilitate regional collaboration: HTA resource hubs and shared infrastructure can strategically catalyze HTA institutionalization in Asia and potentially beyond. Access the scorecard and findings here: https://pubmed.ncbi.nlm.nih.gov/35858879/

FUTURE CONSIDERATIONS

- Invest in supporting regional bodies such as HTAsiaLink and ASEAN to guide countries to establish health priority-setting and resource allocation programs and emphasize rapid reviews, peer referencing, and adaptive HTA to inform rapid decision making.
- Institutionalize PE tracking within health account teams and encourage future investments in technology to drive better health care outcomes.
- Encourage health professionals and decision makers to explore the OneHealth Tool to unlock new opportunities for strategic planning, including by seamlessly integrating OneHealth with existing health information systems to leverage available data and facilitate interoperability. By establishing a feedback loop for the continuous evaluation of the OneHealth Tool, user feedback can contribute to improvements for optimal performance.
- Government finance agencies, international donors, and global health organizations to develop sustainable funding models for HTA activities, facilitate knowledge exchange and collaborative projects, and share best practices in HTA and priority setting for UHC.
- Support the continued adoption of uniform regulatory information management systems with minimum common standards to enable effective, efficient, and timely processes that increase maturity levels and exchange of data as part of regulatory harmonization efforts; in addition, implement common standards for health product registration to advance regulatory harmonization in Asia.
- Establish an international database of COI policies and tools to facilitate cross-country collaboration, share lessons learned on adapting and applying generic COI-related guidance, and supplement existing guidelines and e-Learning opportunities.
- Identify metrics and approaches for evaluating the results of COI policies and strategies.

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RECOMMENDED CITATION

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