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

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Pharmacy in Biratnagar, Nepal. Photo credit: MTaPS Nepal

MTaPS COUNTRY SUMMARY REPORT
NEPAL (2019–2024)

About USAID MTaPS

The US Agency for International Development (USAID) Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program (2018–2024) 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.

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INTRODUCTION

The US Agency for International Development (USAID) Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program (2018–2024) enables low- and middle-income countries 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.

At the country level, the MTaPS approach is adapted to the specific context, national health system–strengthening strategies, and USAID's vision and support. In Nepal, from 2019 to 2024, MTaPS provided technical assistance to the Department of Drug Administration (DDA), Curative Service Division, Quality Standard and Regulation Division, and Ministry of Health and Population (MOHP) to strengthen pharmaceutical-sector governance and the DDA's regulatory capacity, to increase the availability of regulatory information for decision making, to institute performance standards for pharmaceutical management and services in health facilities, and to contain antimicrobial resistance (AMR).

CHALLENGES

- Inadequate DDA capacity, contributing to a low regulatory maturity score as measured with the WHO GBT
- Underperforming regulatory management information system lacking digitalization
- No standards or programs to ensure GPP, GSDP, or good hospital pharmacy practices in the public or private sectors
- Poor medicines management in facilities, compromising access to safe and effective medicines
- Weak and outdated legislation, policy, and regulatory framework for pharmaceutical-sector governance and oversight
- Lack of multisectoral coordination on appropriate antimicrobial use to contain AMR

PARTNERS

- Association of Pharmaceutical Producers of Nepal
- Curative Service Division, Department of Health Services
- Central Institute of Science and Technology (CIST) College
- DDA and branch offices
- Department of Health Services Management Division
- Quality Standard and Regulation Division of MOHP
- District Public Health Service Offices
- Health Journalist Association of Nepal
- Kathmandu University
- MOHP
- MOHP (provincial)
- Ministry of Social Development (provincial)
- Nepal Chemist and Druggist Association
- Nepal Health Professional Council
- Nepal Law Commission
- Nepal Pharmaceutical Association
- Pharmacy Association of Nepal
- USAID implementing partners: Promoting the Quality of Medicines Plus, FHI 360, Global Health Supply Chain-Procurement and Supply Management
- WHO Nepal

COUNTRY CONTEXT

Nepal's steps toward universal health coverage, which have included the establishment of a national health insurance scheme, will require a strong pharmaceutical regulatory system, able to ensure quality health products and related services. The DDA's responsibilities in Nepal include registering and regulating health products, manufacturers, importers, wholesalers, and outlets to ensure access to safe, effective, quality-assured medicines and patient-centered pharmaceutical care. In 2020, the DDA's regulatory system maturity level (ML) was scored at level 1 (some system elements in place) out of 4 (level 4 indicates advanced system performance), as measured by the World Health Organization (WHO) Global Benchmarking Tool (GBT).[1] Contributing to the DDA's ML challenge was a weak digital regulatory management information system (MIS) to produce the analysis that the DDA needs to optimize its own operations and oversee the sector effectively. Moreover, the volume of products (over 12,000) and outlets (over 30,000) exploded in recent years, and the DDA has not expanded its resources or staffing accordingly.

One of the DDA's mandates is to license pharmacies and wholesalers after they fulfill certain regulatory requirements; however, Nepal's regulations and guidelines were outdated and did not align with WHO best practices for good pharmacy practices (GPP) or good storage and distribution practices (GSDP); to achieve GPP, the country needed to build its health care cadres' ability to manage medicines in five domains: storage, ordering and reporting, dispensing, prescribing, and stock management.[2,3]

Nepal also faces the threat of AMR, fueled by inappropriate over-the-counter dispensing, self-medication with antibiotics, and a lack of awareness among dispensers and patients regarding the rational use of antibiotics.

STRATEGIC APPROACH

To help Nepal improve its health outcomes, MTaPS collaborated with the MOHP and the DDA to build the foundation for an up-to-date and efficient DDA, capable of overseeing the growing pharmaceutical sector and regulating it in line with WHO best practices. This effort required strengthening governance through updating the sector's regulatory framework—regulations, codes, and guidelines, including the National Medicines Policy (NMP).

Using system-strengthening approaches to optimize resource allocation, MTaPS worked with the DDA to build organizational and individual capacities to become a more effective regulatory body. By using GBT and other assessment results, MTaPS helped the DDA to identify the steps needed to reach ML3—indicating a well-functioning regulatory system—which led to institutional development and ML action plans. Achieving regulatory maturity also required the DDA to look at options for a new MIS that produces accurate, timely regulatory data to streamline decision making on inspection and product and premises registration and to coordinate its pharmacovigilance system.

MTaPS supported implementation of regulatory requirements in the private and public sector to improve pharmaceutical services and patient-centered care, such as the institution of GPP, GSDP, and good hospital pharmacy practice standards and programs with national guidelines and multi-pronged capacity-strengthening strategies. A critical approach was to customize the evidence-based Supervision, Performance Assessment, and Recognition Strategy (SPARS) and pilot it in health facilities to determine if it improves medicines management cost-effectively. MTaPS also supported the MOHP to analyze the national AMR situation and target media in a campaign to raise public awareness of this critical issue.

KEY ACHIEVEMENTS

2019
- DDA organizational structures analyzed in comparison with other countries' regulatory authority structures.
- Pharmaceutical legislation analysis conducted to determine gaps in pharmaceutical-sector governance.

2020
- WHO GBT assessment conducted to determine DDA's baseline regulatory ML.
- Assessment of DDA's quality management system (QMS) and options analysis for DDA's MIS carried out to create ML action plan.

2021
- DDA reorganization and staffing norms proposed.
- Baseline study completed on adherence to GPP/GSDP guidelines using indicator-based inspection tool.

2022
- NMP, Drug Act, Codes on Sales and Distribution (CSD), and GPP/GSDP guidelines drafted.
- DDA staff competency mapping, capacity-strengthening strategy, and GBT ML action plan developed.

2023
- SPARS pilot study implemented in 352 facilities in 12 districts and 3 provinces to determine effectiveness in strengthening medicines management.
- DDA's new MIS, DAMS-2, rolled out for pharmacy and wholesalers' registration and renewal.

> *"The revised Codes on Sales and Distribution of Drugs and the good practices guidelines will improve the standards of pharmacy and wholesaler practices and ensure safe and effective medicines and health technology products for the Nepali people."*
>
> *Mr. Naryan Prasad Dhakal*
> *Director General, DDA*

KEY RESULTS

Working in collaboration with the DDA, the MOHP, and other stakeholders, MTaPS supported Nepal in achieving the following key results:

Strengthening Pharmaceutical-sector Governance

- DDA reorganization plan, staffing norms, job descriptions, key function workflows, and standard operating procedures (SOPs) finalized, and legislation updated for the DDA's evolution into a mature regulatory authority.
- Critical documents developed, including a revised Drug Act and NMP, six regulations, and three codes to provide the foundation for Nepal's updated regulatory framework and sector-strengthening efforts.
- Clinical trial inspection guidelines and checklist developed in line with international standards and first clinical trial site inspected and approved.

Increasing Institutional and Human Resource Capacity to Regulate Medicines and Other Health Technologies

- DDA regulatory capacity increased from ML1 in 2020 to ML2 in 2023: 100% of GBT ML1 and ML2 indicators and 64% of GBT ML3 indicators were met.
- The DDA's new electronic document filing system and biometric-controlled repositories, which store 70,000 documents, decreased staff time to retrieve a file from days to hours, thus increasing DDA efficiency in dossier review.
- CSD of Drugs updated to add Nepal's first-ever official GPP/GSDP and good hospital pharmacy practices guidelines, demonstrating the government's commitment to improving pharmaceutical practices in the public and private sectors.
- Medicines price regulation assessed and updated (for the first time since 2016), which will contribute to uniform maximum prices and reduced out-of-pocket spending on medicines.
- Capacity of pharmacists strengthened in GPP (n=520) and good hospital pharmacy practices (n=94), respectively; 350 wholesalers trained in GSDP to align with global best practices.
- GPP implementation post-training increased in 10 retail outlets from 57% to 72% (based on 57 indicators); the score for critical licensing indicators increased from 72% to 95% (based on 14 indicators), both demonstrating improved GPP in the private sector.
- Electronic tools designed for DDA's GPP/GSDP regulatory inspections facilitated inspectors' data monitoring, assessment score reproducibility, and analysis of performance data, which revealed trends and targeted interventions needed to increase good practices.
- Registration processes for health technology products strengthened by updating the regulation and guidelines, creating a list of priority health products and developing standard procedures to assess product files.

Staff time to retrieve a file changed from **DAYS to HOURS** due to DDA's new electronic document system.

DDA advanced from **ML1 in 2020 to ML2 in 2023**.

60 health care professionals **trained in ADE reporting** and use of Vigiflow to improve PV.

The percentage of **high-quality ADE reports** rose from **16% to 72%**.

1,100+ SPARS supervisory visits to 347 government health facilities led to improved medicines management.

AMR sensitization of **470+** journalists led to **200+ media reports** to increase public awareness.

- Registration module adapted and integrated into the DDA's new MIS, DAMS-2, which will optimize the DDA's registration process.
- Technical specifications developed for 152 medicines and 22 consumables; these specifications are essential for optimizing procurement processes and assuring the quality of essential medicines and supplies in Nepal's basic health service package.
- Results from an adverse drug event (ADE) reporting assessment, followed by training of 60 health care professionals in ADE reporting and use of Vigiflow (a national pharmacovigilance database to monitor the safety of medicines and vaccines), led to increases in the number of monthly ADE reports (1.5 to 6) and in the percentage of high-quality reports (16% to 72%).

Increasing Availability and Use of Pharmaceutical Information for Decision Making

- Based on evidence from an MTaPS-supported assessment showing that only 6 of 18 maternal, newborn, and child health tracer products had valid registration status, the DDA successfully advocated for a new MIS to increase the efficiency of its product registration process.
- The DDA's decision to design and implement DAMS-2 put them on the path toward streamlined registration and inspection operations and contributed to DDA's overall goal of digitalizing its functions.
- Pilot results and training prepared the MOHP to adopt the PSS Insight v2.0, an indicator-based monitoring tool to measure progress in strengthening national pharmaceutical systems.

Improving Patient-Centered Care to Improve Health Outcomes

- Following more than 1,100 supervisory visits to 347 government health facilities in 12 SPARS pilot districts, the facilities' average medicines management score increased by an impressive 123% and 41 percentage points from baseline with improvements in all 5 areas of medicines management.
- 113 hospital pharmacists from Curative Service Division and Management Division and 60 medicines management supervisors received training in SPARS intervention methods, and MOHP and local officials in pilot districts were sensitized on their implementation roles as part of the transition of SPARS to local government.
- AMR sensitization training of more than 470 journalists resulted in more than 200 evidence-based media reports appearing in newspapers, TV, radio, and social media that will boost community awareness about AMR and the public's role in containing it.

New repositories increase DDA's document management efficiency

The DDA receives hundreds of documents each day, including registration applications and inspection reports that need to be stored securely. Without a suitable storage or indexing system, quickly retrieving documents from piles of thousands was impossible. MTaPS procured 5 sets of repositories with the capacity to hold 70,000 files, supported their installation, including indexing and transferring 50,000 files to the new system, developed SOPs, and trained DDA staff in their use. The repository also has an access-control feature using biometric identification for security. With the repositories, visible changes are under way at the DDA. One remarkable improvement is the speed at which dossiers and application files can now be retrieved. Previously, retrieving these files from storage would take days or weeks, and only a few staff were able to locate them due to inadequate indexing. However, with the installation of repositories and establishment of an indexing system, authorized staff can easily retrieve these documents—sometimes within minutes. This has greatly enhanced staff efficiency and decreased waiting time, thereby improving customers' experience.

File storage before and after repositories installation.
Photo credit: MTaPS Nepal

FEATURED RESOURCES

- Subnational Procurement Practices of Maternal, Newborn, and Child Health Medicines in Nepal (Report)
- Supervision, Performance Assessment, and Recognition Strategy (SPARS) – A Multipronged Intervention for Strengthening Medicines Management (Case study)
- Championing Multi-Stakeholder Engagement for Capacity Strengthening towards AMR Containment in Nepal (Case study)
- Partnering to Spread Awareness on Antibiotic Use to Save Lives in Nepal (video)
- MTaPS Partners with the Nepalese Government on Preventing Misuse of Medicines (video)
- Nepal Champions Appropriate Use of Medicines for Patient Safety and Health Outcomes (video)
- Nepal Promotes Mandatory Billing of Medicines to Improve Patient Safety (video)
- e-Learning courses on GPP and GSDP

Subnational Procurement Practices of Maternal, Newborn, and Child Health Medicines in Nepal

PATHWAY TO SUSTAINABILITY

MTaPS provides technical guidance and supports countries in establishing strategic direction and development of critical capacities on a pathway to sustainable and resilient pharmaceutical systems. Through its activities in country, MTaPS strengthened the capacity of local governments and organizations (public, private, and civil society) for improved, locally led, and more sustainable pharmaceutical service delivery, as highlighted below:

- Nepal's revised CSD with the country's first-ever official GPP and GSDP guidelines form the basis for the DDA's ongoing regulatory training and oversight; the Codes are complemented by public communication materials and e-Learning courses, which, going forward, will be required for pharmacies and wholesalers to receive licensing or renewal in DAMS-2.
- The DDA increased its regulatory capacity and ML through updated laws and policies that form a strong regulatory framework and an internal QMS; with WHO and implementing partner support, the DDA is positioned to continue increasing its ML.
- DAMS-2 contributing to DDA operations; going forward, trained help desk staff will facilitate change management and a local IT vendor will provide maintenance services—putting DAMS-2 operation in local hands without needing MTaPS support.
- The DDA has taken ownership of the capacity-building package on ADEs, giving them the foundation to identify and respond to danger signals to prevent medication-related harm.
- MTaPS-trained tutors from Kathmandu University, along with Curative Service Division staff and subnational stakeholders in 12 districts from 3 provinces oriented on SPARS implementation, have prepared the MOHP to take over and roll out the SPARS program.
- More than 470 newly trained journalists representing all 7 provinces are equipped with AMR knowledge and resources to continue highlighting the issue in the media, thereby further increasing public awareness on AMR containment.

RECOMMENDATIONS

- Establish an MOHP pharmaceutical directorate, initially run with the help of seconded staff/experts, to lead the country's pharmaceutical sector development and oversight.
- Continue strengthening the DDA's GSDP program implementation in government and private sector wholesalers to address recent assessment findings of unnecessarily high prices, weak quality assurance, and low product availability.
- Support implementation of new regulations and policies, including the CSD of Drugs and advocate for approval of drafts, such as the NMP; work with training institutions to integrate the updated policy and new regulations and guidelines into their health/pharmacy curricula to increase health workforce understanding of these documents' importance.
- Implement GPP/GSDP guidelines in the public and private sectors, including retail drug outlets where people illegally access prescription-only medicines, to instill service standards.
- Transition responsibilities to professional bodies for new tutor training and e-Learning for the new GPP/GSDP guidelines and support rollout.
- Roll out the successful SPARS pilot to build medicines management capacity in health facilities and strengthen patient-centered pharmaceutical services.
- Sustain the DDA's effort to achieve GBT ML3 and attain International Organization for Standardization (ISO) 9001:2015 certification by continuing to support its reorganization and QMS function.[4]
- Support the DDA's use of the nascent DAMS-2 and implementation of the additional modules developed under MTaPS.

FUTURE CONSIDERATIONS

- Expand interventions to strengthen medicines management to reach all government health facilities; for example, roll out SPARS nationwide and institutionalize the program by integrating the SPARS facility score into the MOHP's quality monitoring system.
- Further ensure patient safety by promoting complementary regulations and systems, including those related to pharmacovigilance.
- Improve supply chain performance and best practices at all health system levels to guarantee an uninterrupted flow of quality-assured health commodities and foster the transition and capacitation of local governments to act as stewards of the health supply chain.
- Investigate the potential of allowing other pharmaceutical cadres to establish drug shops to counteract Nepal's severe shortage of qualified pharmacists while ensuring pharmaceutical service quality.
- Increase MOHP coordination and support for implementing pharmaceutical sector policies to continue strengthening the different elements of the country's pharmaceutical management system.
- Continue updating the regulatory and legislative framework and investing in functional, well-resourced, mature regulatory systems that will ensure the quality, safety, and efficacy of health commodities.
- Expand efforts to slow the development and spread of AMR by promoting a One Health approach, including multisectoral stakeholder engagement and using proven interventions to strengthen central- and facility-level antimicrobial stewardship programs.
- Support efforts to expand the national health insurance scheme and strengthen its coverage, focusing on essential medicines and health products to improve access.

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