

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

*Improved Access. Improved Services. Better Health Outcomes.*

Approaches and Tools for Strengthening Pharmaceutical Systems

## Ensuring Quality and Safety in Pharmaceuticals System: The Role of Good Governance

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# The importance of good governance in pharmaceutical systems

Poor governance leaves pharmaceutical systems vulnerable to corruption and mismanagement

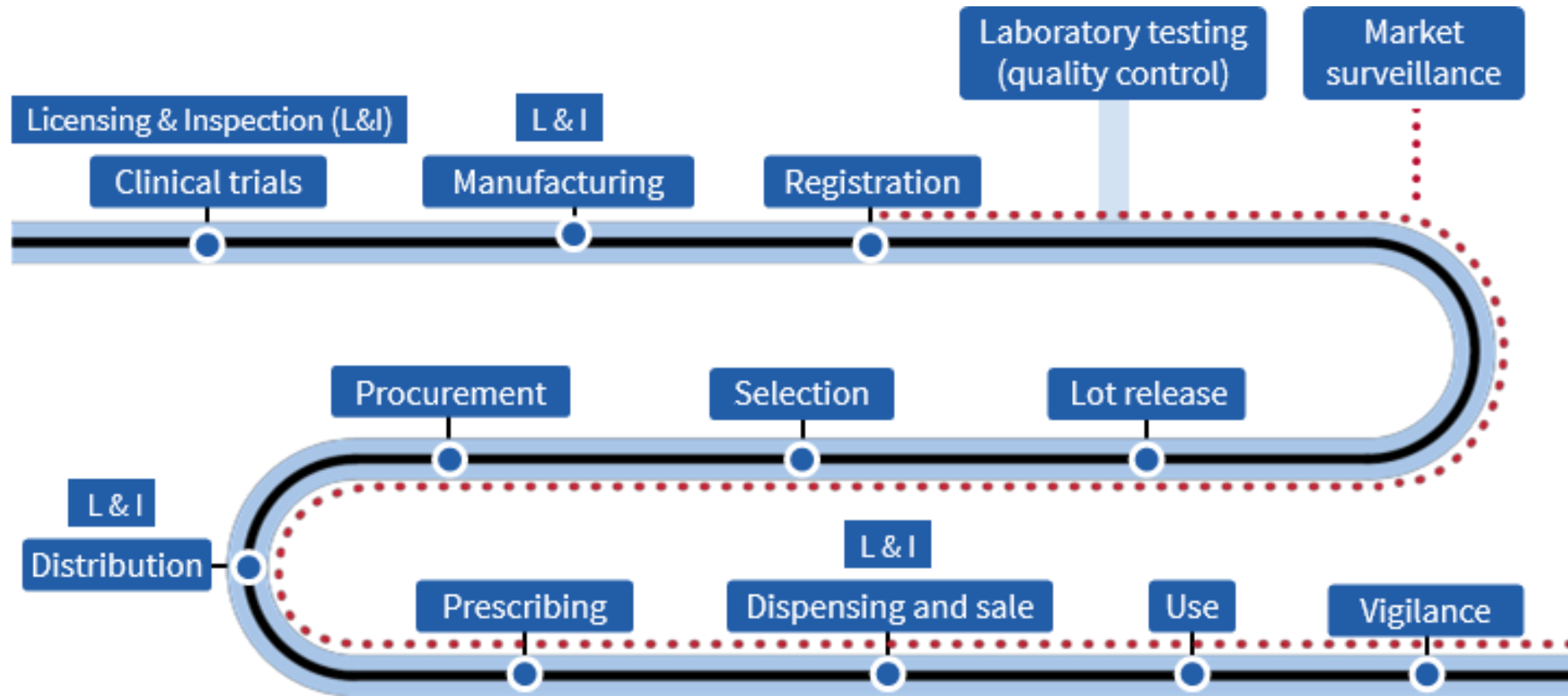


Diagram based on concepts from: [The Many Faces of Corruption: Tracking Vulnerabilities at the Sector Level](#) (page 35) and [WHO Good Governance for Medicines Programme: an innovative approach to prevent corruption in the pharmaceutical sector](#) (page 5).

# Strengthening governance for more resilient and sustainable health systems

Strong governance can:

- Improve medicines **access** and **quality of care**
- Increase **sustainable use** of scarce health system resources
- Promote and maintain **trust** in health systems



# The importance of good governance in pharmaceutical systems



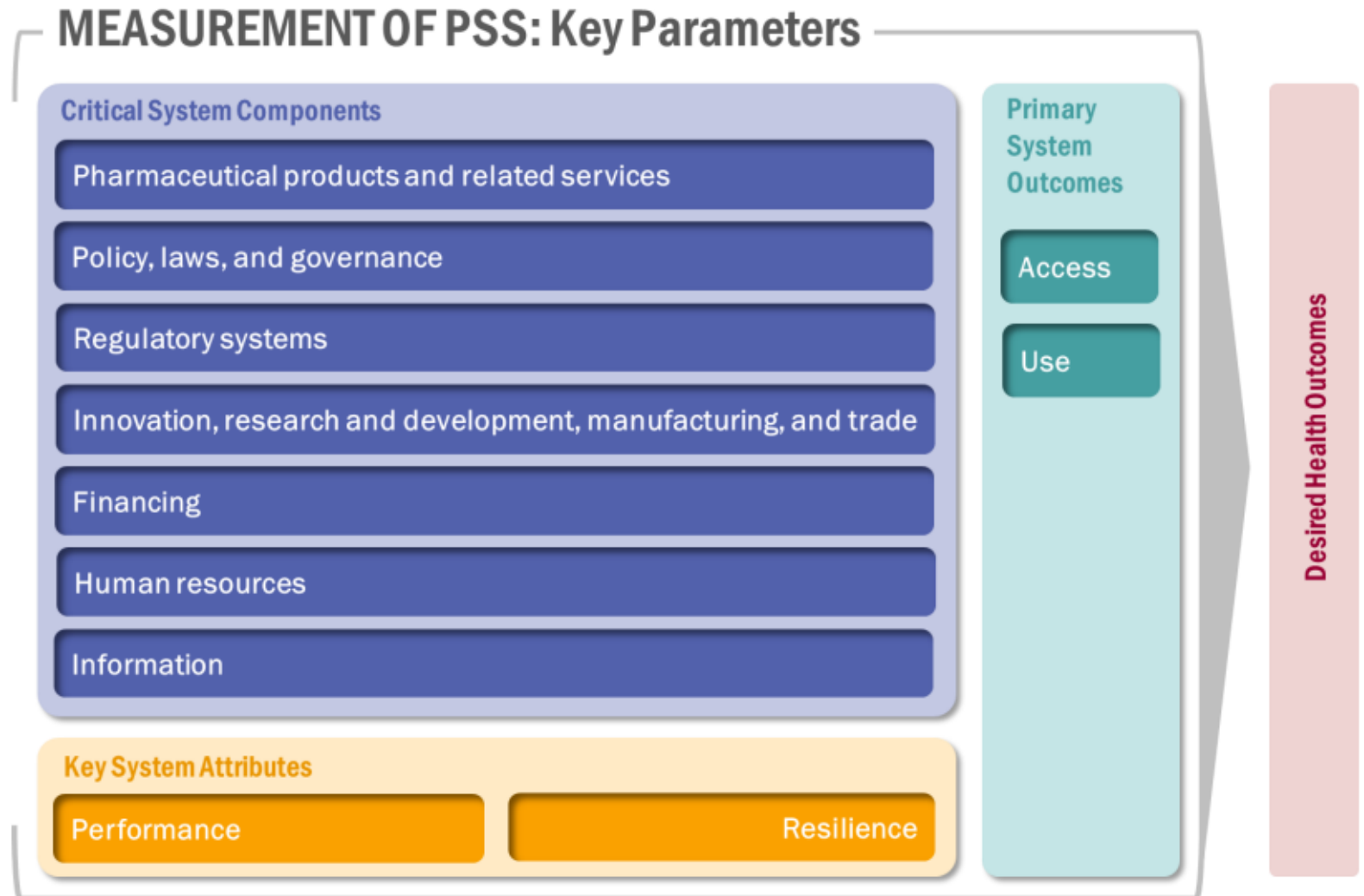
Adapted from UNDP. 1997. Governance for sustainable human development. <http://mirror.undp.org/magnet/policy>

Improving pharmaceutical governance systems can be achieved by:

- Increasing transparency and accountability throughout the pharmaceutical system
- Improving and enforcing evidence-based medicine laws, regulations, policies, guidelines, norms, and standards
- Increasing stakeholder engagement and empowerment, including civil society and consumers
- Working with country stakeholders to identify areas in need of reform in the pharmaceutical system

# Approaches and tools: PSS Insight V2.0

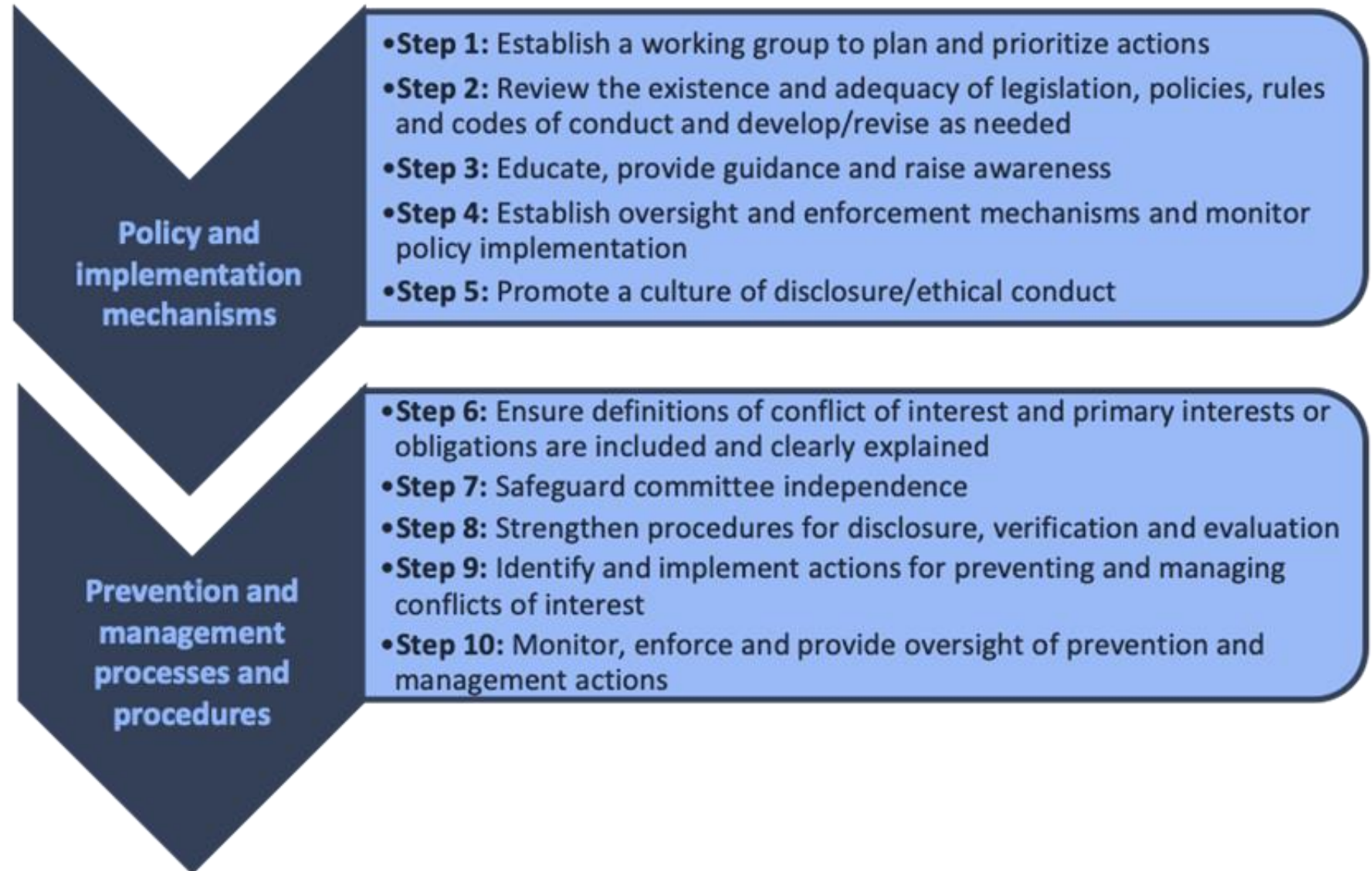
## PSS Insight V2.0— A Framework for Measuring Pharmaceutical Systems Strengthening





# Approaches and Tools: Practical guidance on managing COIs

## A How-to Guide on Prevention and Management of Conflicts of Interest (COIs) for Public Pharmaceutical-Sector Committees in Low- and Middle-Income Countries



# Approaches and tools: Strengthening the capacity of national pharmaceutical services units

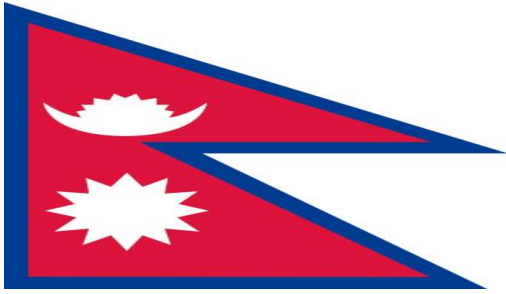
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## **Guidelines on Best Practices for National Pharmaceutical Services Units (NPSUs) in Low-And Middle-Income Countries** *(forthcoming)*

- NPSUs are public sector administrative entities that provide the overarching governance structures responsible for regulating medicines, managing the health supply chain, and formulating and implementing pharmaceutical policies and standards.
- MTaPS is currently conducting case studies to assess NPSUs' roles and capacity needs in three countries. Findings will be used to:
  - Develop guidelines for strengthening capacity of NPSU's to fulfill their mandate.
  - Inform government decisions for strengthening pharmaceutical policies and services to contribute to the Sustainable Development Goals and support the achievement of universal health coverage (UHC).

# Case Studies: Nepal

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- ④ **Department of Drug Administration (DDA) organizational restructuring:** New organizational structure that best supports functional responsibilities in the country's federated system
- ④ **Regulations, rules, and guidelines updated.**
  - Drug and Health Product Regulation, Inspection Regulation, and Drug and Health Product Standard Regulation being updated to provide a solid legal framework for DDA to perform its critical functions effectively and sustainably
  - 1995 Nepal national medicine policy revised
- ④ **New e-Learning materials** for Good Pharmacy Practices (GPP) and Good Storage And Distribution Practices (GSDP).



# Case studies: Strengthening COI management

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## Managing Conflicts of Interest

The USAID MTaPS Program, in partnership with the WHO Department of Health Products Policy and Standards, conducted a virtual learning exchange on preventing and managing COIs in public pharmaceutical systems

- MTaPS successfully engaged 36 policymakers, managers, committee conveners, and chairs from 16 countries on the prevention and management of COIs in national pharmaceutical systems.
- This was the first use of the manual *Managing Conflicts of Interest: A how-to guide for public pharmaceutical sector committees in low- and middle-income countries*.
- Several participants developed action plans and were able to take some preliminary steps toward improving the prevention and management of COIs in their local organization or setting.

# How can you apply these approaches and tools?

- **Managing conflicts of interest: a how-to guide for public pharmaceutical-sector committees in low- and middle-income countries** (WHO, 2022): This manual highlights 10 practical steps for improving COI policy, prevention, and management in the public pharmaceutical sector.
- **PSS Insight v2.0—A Framework and Indicators for Measuring Pharmaceutical Systems Strengthening (MTaPS, 2021)**: PSS Insight provides a comprehensive tool for evaluating the key components of a pharmaceutical system.
- **National Pharmaceutical Services Units (NPSUs) In Low-And Middle-Income Countries** (MTaPS, forthcoming): MTAps is currently developing recommendations for the minimal (most essential) structure (both unit and relational), roles, responsibilities, and methods for operation.



# How can you apply these approaches and tools?

- **Advocacy Brief on Social Accountability to Improve Access to and Appropriate Use of Quality Maternal, Newborn, and Child Health-Related Medical Products** (MTaPS, forthcoming)
- **Engaging Civil Society in Social Accountability to Improve Access to and Appropriate Use of Quality Maternal, Newborn, and Child Health-Related Medical Products** (MTaPS, 2021): This discussion paper evaluates the experiences and lessons derived from social accountability research and interventions, with the aim of recognizing the policy and practical implications for initiatives that aim to involve civil society in increasing access to and appropriate utilization of quality maternal and child health medical products.



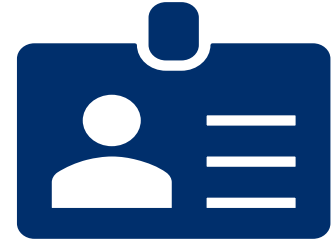
# Additional e-learning resources

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- **Good Governance in the Management of Medicines**: This course provides learners with an understanding of the importance of good governance throughout the process of pharmaceutical management. Key interventions that can promote good governance are discussed, as well as important considerations when working with countries to implement improvement strategies.
- **Pharmaceutical Systems Strengthening I 01 (available in English and in French)**: This course introduces learners to the basic principles of PSS, including how addressing pharmaceutical system problems advances universal health coverage; combats antimicrobial resistance, HIV and AIDS, malaria, tuberculosis, and other public health threats; and promotes maternal and child health.
- **Recording of COI informational session**: Available upon request at [HPS@who.int](mailto:HPS@who.int)
- **COI e-learning course** (WHO, forthcoming)



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