

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 Pharmaceutical Systems: The Role of Good Governance

Technical Brief | February 2023

Why is good governance important in pharmaceutical systems?

A pharmaceutical system is a complex network of interactions that spans from research and development to service delivery and involves both the private and public sectors.¹ It encompasses all structures, individuals, resources, processes, and interactions within the broader health system to ensure equitable and timely access to safe, effective, and high-quality pharmaceutical products and services that promote appropriate and cost-effective use to improve health outcomes.² Promoting transparency and accountability are crucial for improving access to essential medicines and strengthening health systems to achieve universal health coverage (UHC).

Ensuring the efficient and effective operation of the pharmaceutical system involves coordinating various interdependent processes, including selection, procurement, distribution, and activities that support the safe and appropriate use of medicines.³ These processes depend on robust management support

systems, including organizational, financial, information, and human resources management, and appropriate policies, laws, and regulations. However, inadequate governance within health systems can create opportunities for corruption and mismanagement to go unnoticed.⁴ The pharmaceutical sector is particularly susceptible to fraud and corrupt practices, and the adverse effects of poor governance in this area can be significant.

The concept of good governance in the pharmaceutical sector encompasses a wide range of principles, including consensus orientation, accountability (including social accountability through civil society engagement), transparency, responsiveness, equity, inclusiveness, effectiveness, efficiency, adherence to the rule of law, and participation. Governance plays a critical role in minimizing opportunities for corruption and mitigating other system inefficiencies. It also shapes the ability of the health system in any country to respond to challenges. Improving governance in pharmaceutical systems takes time. The USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program supports countries in enhancing governance within the pharmaceutical sector.

¹ Grundy Q, Parker L, Wong A. et al. 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. *Global Health*. 2022. 18, 33. <https://doi.org/10.1186/s12992-022-00822-8>

² Hafner T, Walkowiak H, Lee D, Aboagye-Nyame F. Defining pharmaceutical systems strengthening: concepts to enable measurement. *Health Policy Plan*. 2017;32(4):572-584. <https://doi.org/10.1093/heapol/czw153>

³ Soucy Brown M, Wirtz V, Hafner T, et al. PSS Insight v2.0—A Framework and Indicators for Measuring Pharmaceutical Systems Strengthening. May 2021. Submitted to the US Agency for International Development by the USAID MTaPS Program. Arlington, VA: Management Sciences for Health, Inc.

⁴ Kohler JC, Mackey TK, Ovtcharenko N. Why the MDGs need good governance in pharmaceutical systems to promote global health. *BMC Public Health*. 2014. 14, 63. <https://doi.org/10.1186/1471-2458-14-63>

Our approach aligns with the objectives of USAID's Vision for Health Systems Strengthening and the global Sustainable Development Goal of increasing access to essential medicines and health technologies.⁵ Improving pharmaceutical governance systems can be achieved by:

- Increasing transparency and accountability throughout the pharmaceutical system
- Improving and enforcing evidence-based medicines 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 sector

In this document, we present applicable tools and approaches used by MTaPS to develop aspects of good governance in pharmaceutical systems and describe how other organizations can apply them in their context.

Approaches and tools for good governance

PSS (pharmaceutical systems strengthening) Insight v2.0

PSS Insight is a comprehensive tool for evaluating key components of a pharmaceutical system and its capacity for improvement. PSS Insight v2.0 is versatile and easy to implement and can assist stakeholders in low- and middle-income countries (LMICs) in assessing and strengthening their national pharmaceutical systems. PSS Insight v2.0 integrates indicators from various components and incorporates measures from multiple domains of pharmaceutical systems. This integrated approach provides a more holistic understanding of the system's overall functioning, elements of which are typically tracked separately. The measurement framework for PSS Insight is illustrated in figure I, with suggested indicators and data sources proposed for components, attributes, and outcomes.

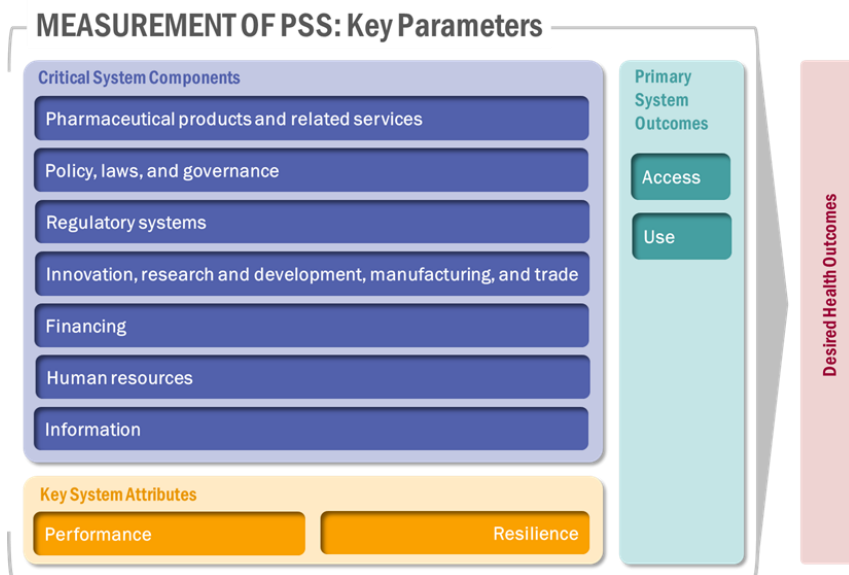


Figure I. PSS measurement framework

- **PSS Insight v2.0 technical brief (forthcoming):** This brief will provide a set of defined indicators and summarize how they can be used to measure PSS.
- **PSS Insight v2.0 data collection and analysis software (forthcoming):** This freely available software will provide a plug-and-play solution to collect and analyze PSS Insight indicators.

⁵ USAID. USAID's Vision for Health Systems Strengthening (2015–2019).

Preventing and managing COIs for public pharmaceutical sector committees in LMICs

An essential aspect of good governance is the effective prevention and management of conflicts of interest (COIs).⁶ A recent study supported by MTaPS conducted in 10 countries identified common gaps in the governance of many pharmaceutical systems, including the lack of established practices for preventing and managing COIs.⁷ To address this issue, the USAID MTaPS Program, in collaboration with the World Health Organization (WHO), has developed a manual for public pharmaceutical-sector committees in LMICs. The manual, entitled "Managing Conflicts of Interest in Public Pharmaceutical Decision-Making Committees," highlights 10 critical steps for improving COI policy, prevention, and management.⁸ The 10 steps outlined in the manual are not intended to be followed in a specific sequential order but rather serve as a guide for committees to assess and improve their COI management practices.

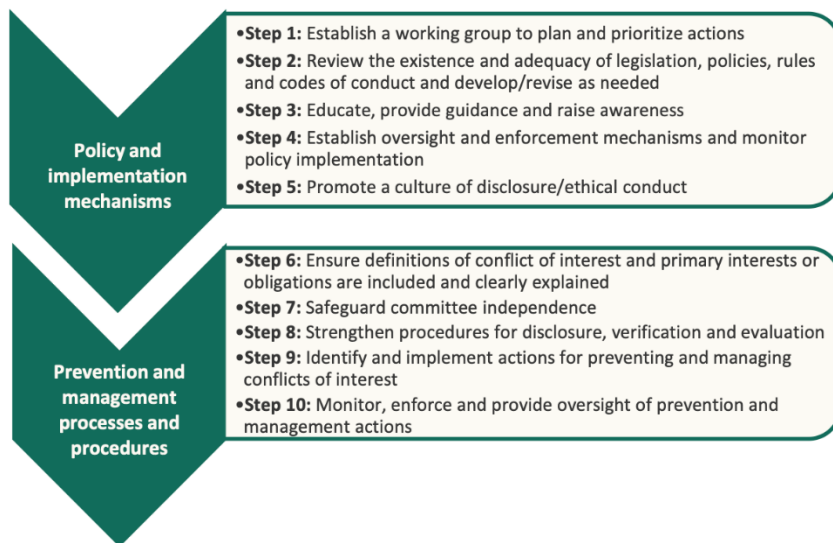


Figure 2. Ten steps for improving the prevention and management of COIs⁸

The practical steps include strategies for policy implementation as well as for prevention and management processes. The steps mark a starting point for evaluating what currently exists in a country and how to build on or develop COI policies and processes.

Best practices for NPSUs in LMICs

National pharmaceutical services units (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. Their primary objective is to ensure equitable, timely, and affordable access to safe, effective, and quality pharmaceutical products and related services across the country, while promoting their appropriate and cost-effective use. MTaPS is currently conducting a case study to assess the current status of NPSUs in various countries. This information will be used to provide guidance on recommended practices for countries to consider as they work to improve the quality of and access to pharmaceutical services within their respective contexts.

⁶ Demmke C, Paulini M, Autioniemi J, & Lenner F. The effectiveness of conflict of interest policies in the EU-Member States. European Parliament, 2020. [https://www.europarl.europa.eu/RegData/etudes/STUD/2020/651697/IPOL_STU\(2020\)651697_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/STUD/2020/651697/IPOL_STU(2020)651697_EN.pdf)

⁷ WHO. Conflict of interest management policies and practices in the public pharmaceutical sector in the WHO South-East Asia Region. Delhi: World Health Organization Regional Office for South-East Asia; 2022. Available at <https://www.who.int/southeastasia/internal-publications-detail/conflict-of-interest-management-policies-and-practices-in-the-public-pharmaceutical-sector-in-the-who-south-east-asia-region>

⁸ WHO. (2022). Managing conflicts of interest: a how-to guide for public pharmaceutical-sector committees in low- and middle-income countries. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO. Available at <https://apps.who.int/iris/bitstream/handle/10665/363124/9789240057982-eng.pdf>

- **NPSU case studies (forthcoming):** These case studies will offer a comprehensive examination of the present state of NPSUs to provide a clear understanding of the status and challenges faced by various countries to inform future decisions and improve their operations.
- **NPSU guidance (forthcoming):** These guidelines will provide best practices for countries to implement as they strive to enhance both the quality and availability of pharmaceutical services within their contexts.

Case studies on governance

Strengthening governance in Nepal

In Nepal, MTaPS supported policy, legislative, and system revision and implementation at the Department of Drug Administration (DDA), including application to the private pharmaceutical sector. As a result, after extensive consultations, the revised draft of the National Medicines Policy (NMP) and the Drug and Health Product Bill were finalized along with related codes, guidelines, and regulations. In addition, MTaPS also supported the development of e-learning materials for Good Pharmacy Practices and Good Storage and Distribution Practices. The primary key elements of activity included:

- **DDA organizational restructuring:** MTaPS conducted two trainings: a five-day session on vaccine dossier evaluation and a one-day workshop on integrating technical standards and guidelines for medical product registration. Implementation of the DDA training plan will continue in the upcoming fiscal year, as enhancing the skills and abilities of DDA staff is crucial in elevating the regulatory agency's level of maturity in Nepal.
- **Update the regulations, rules, and guidelines:** DDA and MTaPS have started drafting the Drug and Health Product Regulation, Inspection Regulation, and Drug and Health Product Standard Regulation to update regulatory documents and provide a solid legal framework for DDA to perform its critical functions effectively and sustainably in Nepal.
- **Revise and update the Nepal NMP:** MTaPS, in close collaboration with the National Medicine

Policy Steering Committee, DDA management, NMP technical working group, WHO, and other stakeholders, finalized the policy options analysis and updated the draft to replace the 1995 NMP. In September 2022, both documents were presented and reviewed at a high-level NMP workshop with over 70 policy makers and national stakeholders organized by the Ministry of Health and Population in partnership with MTaPS.

Managing COIs

USAID MTaPS, in partnership with the WHO Department of Health Products Policy and Standards, conducted a virtual learning exchange on the Joint Learning Network to guide on preventing and managing COIs in the public pharmaceutical systems of LMICs, through application of the manual "Managing Conflicts of Interest in Public Pharmaceutical Decision-Making Committees." A total of 36 participants from 12 countries attended the virtual learning exchange. After the exchange, MTaPS and WHO delivered an informational session to share the recently published manual and encourage country application. During the session, country representatives shared their experiences with managing COIs with reference to applying the recently published manual.

A member of the National Pharmaceutical Regulatory Agency in Malaysia described the challenges faced by the regulatory body. He stated, "As gatekeepers of products to be registered in Malaysia, the agency experiences significant pressure from stakeholders with vested interests to obtain an approval or expedited product evaluation." Also, he noted that pharmaceutical experts on hospital and university committees tend to favor grants and research that can affect research funding or elevate the organization's status. To address these challenges, the agency now holds regular meetings to raise awareness of COIs and involves technical and organizational stakeholders in decision-making processes.

In Uganda, the National Drug Authority's members highlighted the challenges due to a competitive labor market with a shortage of registered pharmaceutical professionals and an abundance of pharmacies. The need for implementing techniques and processes to establish a culture that continuously works to prevent COIs in the hiring process was emphasized.

How can organizations apply these approaches and tools?

Several resources exist to equip organizations with the knowledge and tools necessary to actively strengthen aspects of governance throughout their pharmaceutical system.

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 is a comprehensive tool for evaluating the key components of a pharmaceutical system. By conducting a detailed analysis of the various elements that make up a pharmaceutical system, PSS Insight aims to identify areas where improvements can be made to increase the overall effectiveness and efficiency of the system.
- [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 reviews the experiences and lessons derived from social accountability research and interventions to identify policy and practical implications for initiatives to engage civil society in increasing access to and appropriate use of quality maternal and child health medical products.
- NPSUs in LMICs (MTaPS, forthcoming): MTAps is currently developing recommendations for the minimal (most essential) structure (both unit and relational), roles, responsibilities, and methods for operation.
- Advocacy Brief on Social Accountability to Improve Access to and Appropriate Use of Quality Maternal, Newborn, and Child Health-Related Medical Products (MTaPS, forthcoming)

Additional readings and resources

- [Conflict of interest management policies and practices in the public pharmaceutical sector in the WHO South-East Asia Region](#) (WHO 2022)
- [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](#) (Grundy et al. 2022)
- [Managing Conflicts of Interest: A Practical Application in Pharmaceutical Sector Committees](#) (November 2022)
- [Defining pharmaceutical systems strengthening: concepts to enable measurement](#) (Hafner et al. 2016)
- [Why the MDGs need good governance in pharmaceutical systems to promote global health](#) (Kohler et al. 2014)

e-Learning resources

- [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 101](#) (available in [English](#) and in [French](#)): This course introduces learners to the basic principles of PSS, including how addressing pharmaceutical system problems advances UHC; 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
- COI e-learning course (WHO, forthcoming)

Contact

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About USAID MTAps:

The USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program (2018–2023) enables low- and middle-income countries to strengthen their pharmaceutical systems, which is pivotal to better health outcomes and higher-performing health systems. 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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