Strengthening Approaches to Managing and Preventing Conflicts of Interest to Increase the Integrity of Health Value Chains

USAID MEDICINES, TECHNOLOGIES, AND PHARMACEUTICAL SERVICES (MTaPS) PROGRAM
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Context and Motivation

- Improvements in health value chains and accompanying pharmacy services are essential for enhancing the **efficiency, accessibility, and quality of health care delivery**.

- Health value chains, with their numerous decision points and significant economic value, are highly **susceptible to conflicts of interest (COIs).** Effective management and prevention of COIs are essential to ensure the **efficient use of limited resources**.

- Improving health value chains requires streamlining processes, reducing waste, and enhancing service coordination, particularly **where COIs may affect resource efficiency**.

- Taking **coordinated action** across elements of the health value chain and pharmacy services is necessary to reduce the risk that COIs compromise the **integrity of the decision-making process.**

Methodology

COI Gap Analysis (2022)

- Analysis of **45 policy and regulatory documents** and **21 key informant interviews** underscored the need to strengthen COI management to **foster decision-making integrity and build public trust in pharmaceutical processes.**

SCAN TO ACCESS THE STUDY:
Disclosure, transparency, and accountability: a qualitative survey of public sector pharmaceutical committee conflict-of-interest policies in the World Health Organization SouthEast Asia Region

A **two-stage** iterative approach of research, tool development, stakeholder feedback, revision, and global dissemination of tools was used **from June 2022 to January 2024**.

1. **MTaPS, in collaboration with the World Health Organization (WHO) Division of Medicines and Health Products**, developed practical guidance to prevent and manage COIs in public pharmaceutical systems in low- and middle-income countries (LMICs).

  - A virtual learning exchange was held through the **Joint Learning Network for Universal Health Coverage** to engage **36 participants** from **12 LMICs** and have them develop an action plan.

SCAN TO ACCESS THE MANUAL:
Managing conflicts of interest: A how-to guide for public pharmaceutical-sector committees in low- and middle-income countries (LMICs)

2. **e-Learning course on OpenWHO**

  - To support the manual, an e-learning course was developed in conjunction with a WHO technical expert.

  - Participants in the previously held JLN virtual learning exchange provided feedback in July 2023 indicating that the course's key takeaways would be useful for **organizational compliance, policy development, and decision-making.**

SCAN TO ACCESS THE COURSE:
Managing Conflict of Interest in National Pharmaceutical Systems
(45 minutes to complete)

Results

The **COI manual** focuses on public pharmaceutical committees and agencies to help close gaps in the integrity of their decision-making processes.

Ten steps for improving the prevention and management of COIs

Policy and implementation mechanisms	**Step 1**: Establish a working group to plan and prioritize actions
	Step 2: Review the existence and adequacy of legislation, policies, rules, and codes of conduct and develop/revise as needed
	Step 3: Educate, provide guidance, and raise awareness
	Step 4: Establish oversight and enforcement mechanisms and monitor policy implementation
	Step 5: Promote a culture of disclosure/ethical conduct
Prevention and management processes and procedures	**Step 6**: Ensure definitions of conflict of interest and primary interests or obligations are included and clearly explained
	Step 7: Safeguard committee independence
	Step 8: Strengthen procedures for disclosure, verification, and evaluation
	Step 9: Identify and implement actions for preventing and managing conflicts of interest
	Step 10: Monitor, enforce, and provide oversight of prevention and management actions

A member of the National Pharmaceutical Regulatory Agency in Malaysia explained the challenges faced by the regulatory body:

> *Being the gatekeeper to products that are going to be registered in Malaysia, we do face quite a lot of pressures from parties with vested interests to get the products approved or at least get an evaluation of the product."*

To combat this, the agency now holds regular meetings involving both technical and organizational stakeholders to increase awareness about COIs and ensure a multi-tier effort to counter their influence in the decision-making process.

1,682 OpenWHO COI course certificates issued between October 2023 and July 2024

Enrollment in the COI course was primarily from LMICs; **India, Kenya, Malaysia, Nigeria, and Pakistan** were the top five countries represented among participants.

The **National Pharmaceutical Regulatory Agency** of the Ministry of Health in Malaysia **committed to making the course mandatory** for all current and new inspectors.

Conclusion

Future areas of work across LMICs to improve public pharmaceutical policy and decision-making

Building on MTaPS' experience, key areas for further action by all stakeholders include:

- Providing a safer environment for whistleblowers who report COI risks and effectively **implementing legislation** that protects them
- Identifying metrics and approaches **for evaluating the results of COI policies** and strategies
- **Disseminating the COI manual and the OpenWHO e-learning course** to encourage the integration of COI-supportive approaches into regular work practices