Pharmaceutical Systems Strengthening

Skills Workshop

GHSC Summit 2022
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Pharmaceutical Systems Strengthening: How to Strengthen this Key Subsystem of the Health System
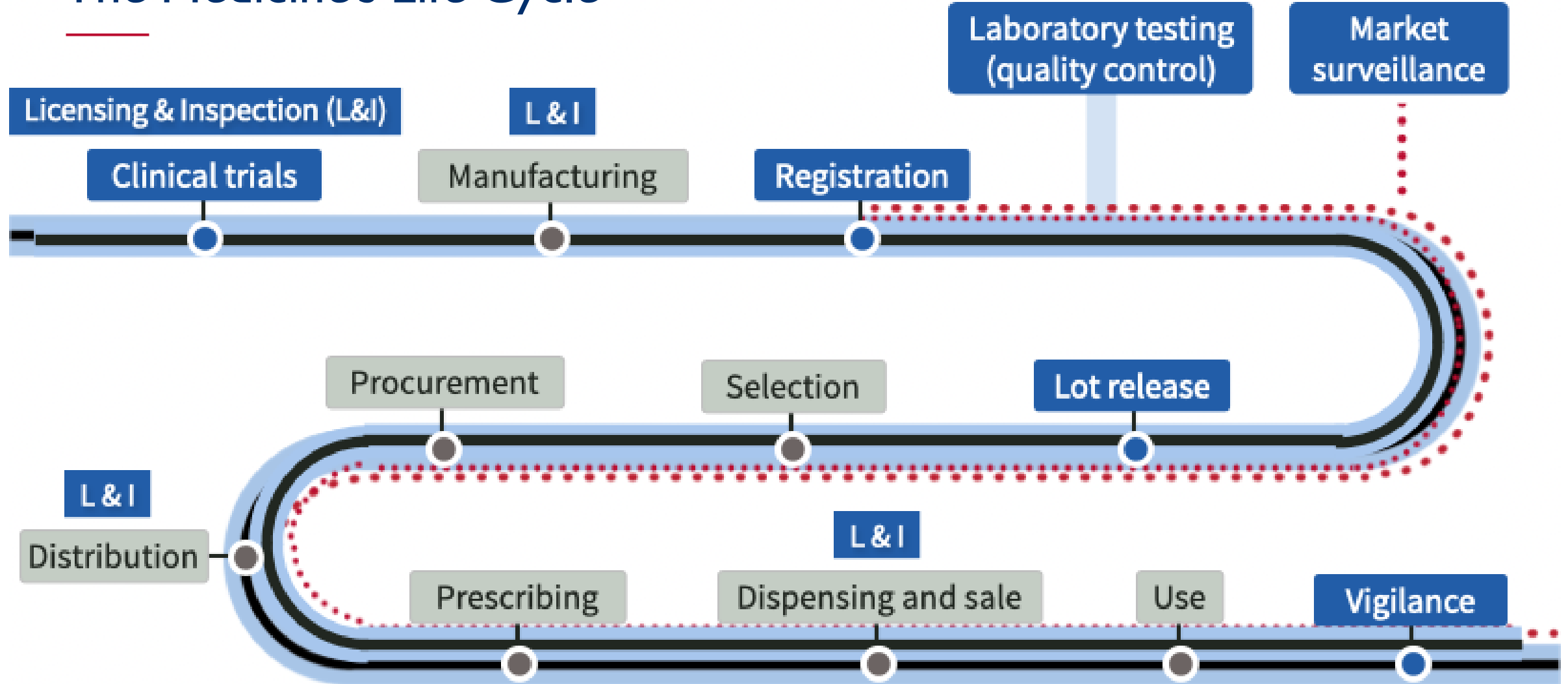
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The Medicine's Life Cycle

Licensing & Inspection (L&I)

L & I

Clinical trials

Manufacturing

Registration

Laboratory testing (quality control)

Market surveillance

Procurement

Selection

Lot release

L & I

Distribution

L & I

Prescribing

Dispensing and sale

Use

Vigilance

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).*

Pharmaceutical Systems Strengthening

Supply Chain is Part of PSS

- Pharmaceutical System

- Pharmaceutical Management System

- Pharmaceutical Supply System

- Pharmaceutical Sector

- Medical Products Building Block (WHO Model)

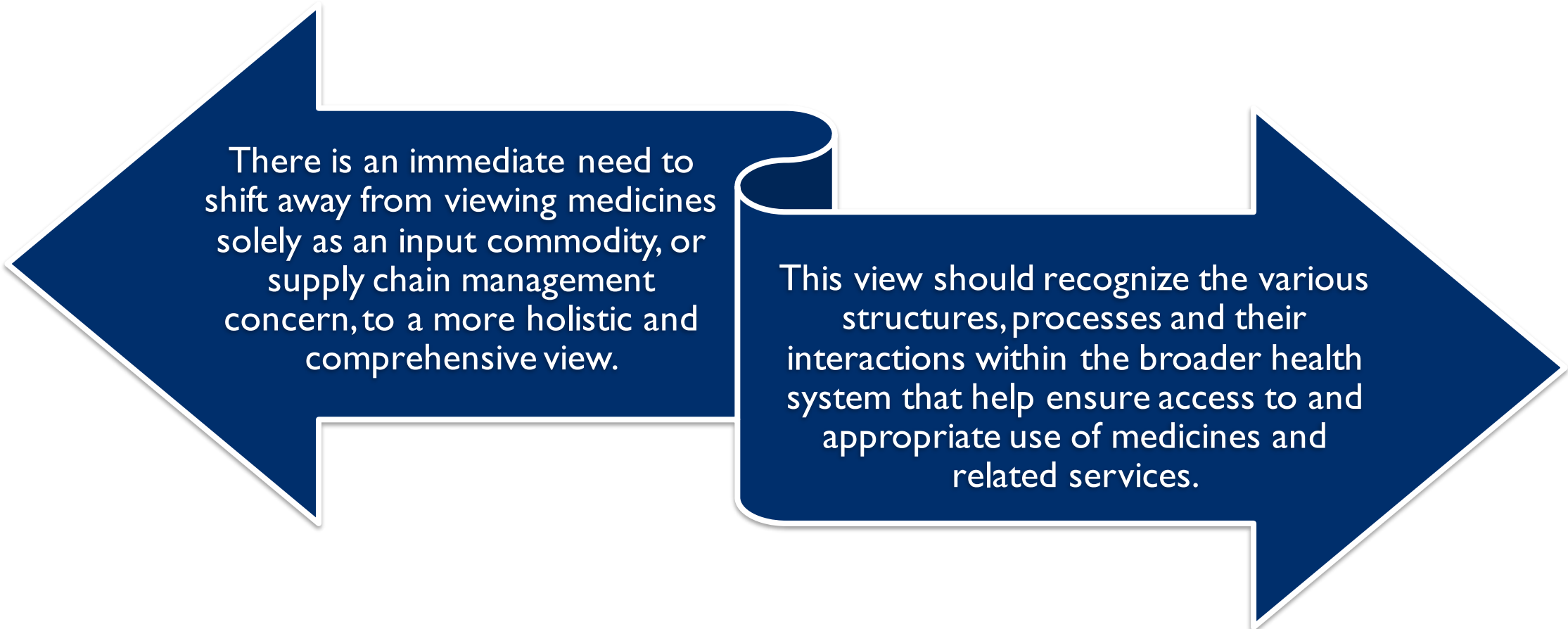# Supply Chain Management ≠ Pharmaceutical Management

- **Supply Chain Management**

  – Addresses factors that influence flows of medicines, funds and information for **availability**

  – Objectives are to optimize supply and demand visibility, velocity and minimize variability in supply chains.

- **Pharmaceutical Management**

  – Addresses factors that influence medicine **availability and** *accessibility, acceptability, affordability and use.*

  – Broad objectives are to ensure access (availability, affordability, accessibility, acceptability and quality), patient safety, and appropriate use.
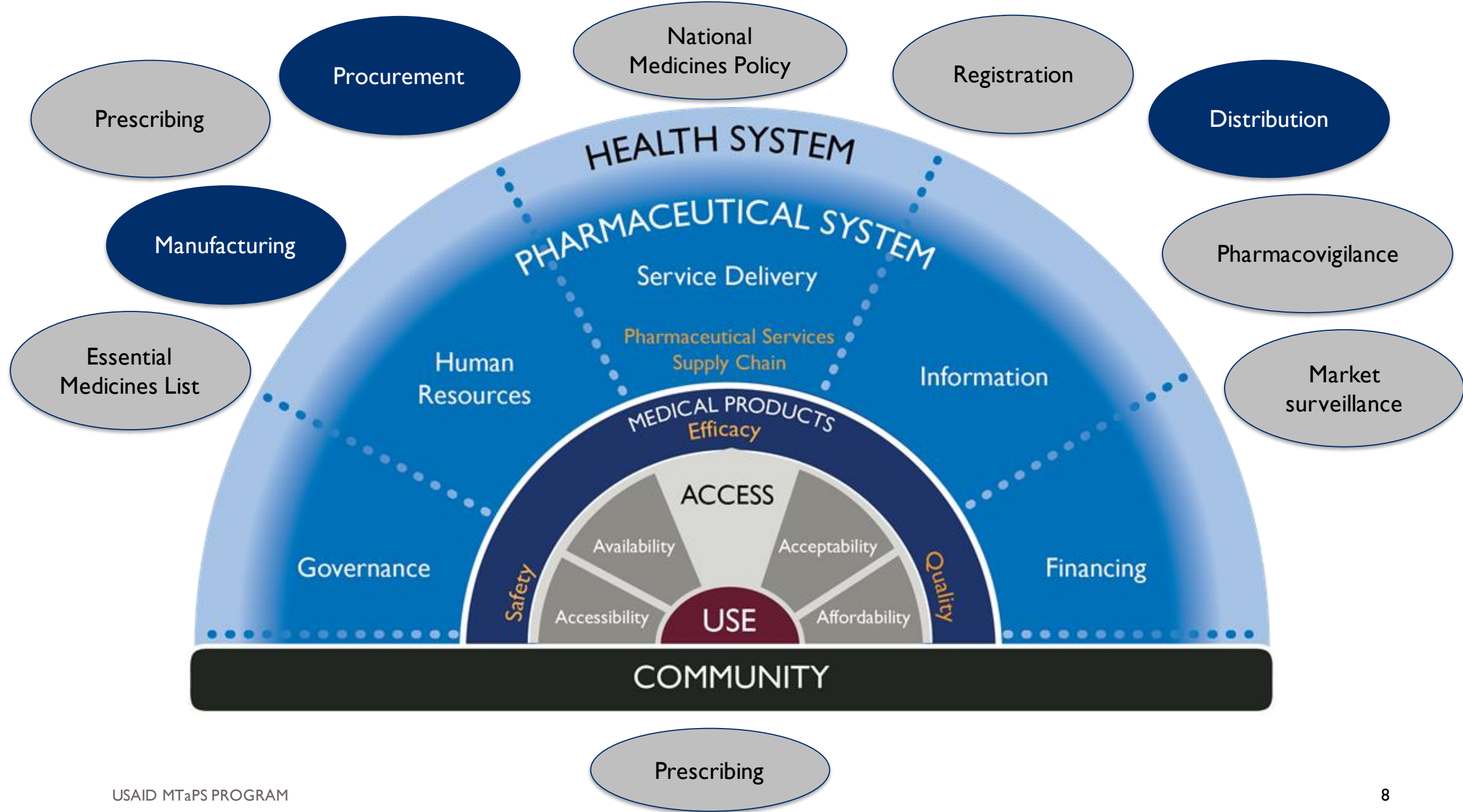
Pharmaceutical Systems Strengthening

There is an immediate need to shift away from viewing medicines solely as an input commodity, or supply chain management concern, to a more holistic and comprehensive view.

This view should recognize the various structures, processes and their interactions within the broader health system that help ensure access to and appropriate use of medicines and related services.

Source: Hafner, T., Banda, M., Kohler, J. et al. Integrating pharmaceutical systems strengthening in the current global health scenario: three 'uncomfortable truths'. J of Pharm Policy and Pract 13, 38 (2020).

Today's Focus will be on Three PSS Interventions:

1. **Regulatory Information Management Systems (RIMS) to support pharmacy regulation (Pharmadex), and pharmacovigilance (PViMS) systems**

2. **Governance on PSS, Conflict of Interest (COI) tools to use in PSS**

3. **Open access PSS E-Learning Modules**

Questions to consider:

- What are the issues these tools seek to address?

- How can these tools can help?

- How can you use the tools in your context?

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Regulatory Information Management Systems

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Why are regulatory information management systems necessary?

- Regulatory systems are a critical component of the broader pharmaceutical system, ensuring the quality, safety, and efficacy of medical products circulating on the market

- Regulatory information management systems are critical for streamlining data collection and analysis and helping countries make evidence-based decisions

MTaPS' approach

- Strengthen human and institutional capacity

- Promote transparency and accountability

- Utilize technology for regulatory compliance and monitoring

- Support interoperability of regulatory data among countries

- Support coordination and advocacy efforts for regional harmonization

Approach and Tools

Pharmadex: a web-based tool that helps streamline and track medicines registration and ensures that products are available and safe

PharmacoVigilance Monitoring System (PViMS): a web-based application to monitor the safety of medicines, including identifying potential adverse events

Digitalization of regulatory information management systems: MTaPS and the USAID-funded Promoting the Quality of Medicines Plus Program jointly developed a guidance document providing a reference pathway for countries to digitalize their regulatory information management systems

Country example: Mozambique

Training on Good Review Practices in Mozambique. Photo credit: Eunice Dias Seni

MTaPS supported the country's national medicines regulatory authority (ANARME) to implement Pharmadex, enhancing it to meet the country's needs

MTaPS supported the use of PViMS so that data entered at the facility level are available at the central level for both monitoring and decision-making
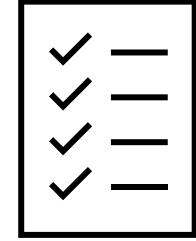
MTaPS supported ANARME to establish an activity surveillance system for the newly introduced medicines in the national HIV and TB programs

Expected outcomes include:
- Improved customer service
- Reduced registration timelines
- Increased availability of data for decision-making

Country example: Nepal

- To support the Department of Drug Administration (DDA) to become a functional authority with an effective regulatory information management system and control of the medical products market, MTaPS:

  - Is helping to customize Pharmadex to increase the Department of Drug Administration's (DDA) efficiency and improve the department's use of data

  - Finalized and implemented the registration module, which is expected to improve the DDA's registration functions

Resources

- Management Sciences for Health. *OpenRIMS*. https://www.openrims.org/

- USAID MTaPS. *Information for decision-making*. https://www.mtapsprogram.org/wp-content/uploads/2021/03/FactSheets_MTaPS_IS-in-Pharmaceutical-Services_052620.pdf

- USAID MTaPS. *Pharmaceutical regulatory systems*. https://www.mtapsprogram.org/wp-content/uploads/2021/03/FactSheets_MTaPS_Pharmaceutical-Regulatory-Systems_051920.pdf

- USAID MTaPS. *Pharmadex*. https://www.mtapsprogram.org/our-resources/pharmadex/

- USAID MTaPS. *PViMS*. https://www.mtapsprogram.org/our-resources/pvims/

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Governance in Pharmaceutical Systems

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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

MTaPS' Approach

- Increase transparency and accountability throughout the pharmaceutical system

- Improve and enforce evidence-based medicines policies, laws, regulations, guidelines, norms, and standards

- Increase stakeholder engagement and empowerment, including civil society and consumers

- Work with country stakeholders to identify areas in need of reform in the pharmaceutical sector

Public pharmaceutical decision-making is vulnerable to conflicts of interest (COIs)

"A conflict of interest results from activities or relationships that compromise an individual's independent judgment or accountability to a party they are obligated to serve."

- Rodwin (2017)

- Risk of secondary interests compromising public pharmaceutical decision-making

  - Pharmaceutical systems involve extensive interactions between the private and the public sector

  - Private sector interests seek to influence decisions about reimbursement, procurement, pricing and how health products are used

  - Relationships with the private sector can give rise to COIs

  - Countries that have just a small pool of expertise may have difficulty identifying experts without COIs

- Both COIs and the perception of COIs pose particular challenges

Practical guidance on preventing and managing COIs

- In collaboration with MTaPS, the World Health Organization developed the manual *Managing Conflicts of Interest: A how-to guide for public pharmaceutical sector committees in low- and middle-income countries*

- MTaPS hosted a learning exchange with policymakers, managers, committee conveners, and chairs to reflect on and apply guiding principles and good practices for COI prevention and management

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

Source: WHO 2022

Resources

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- Flores, W., Briggs, J., Crow, R., & Walkowiak, H. (2021). *Engaging civil society in social accountability to improve access to and appropriate use of quality maternal, newborn, and child health-related medical products: a discussion paper.* Prepared for USAID by the USAID MTaPS Program. https://bit.ly/social_accountability

- Grundy, Q., Parker, L., Wong, A., Fusire, T., Dimancesco, D., Tisocki, K., Walkowiak, H., Vian, T. & Kohler, J. (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. *Globalization and Health, 18*:13. https://doi.org/10.1186/s12992-022-00822-8

- Walkowiak, H., Hafner, T., Putter, S. J. (2018). *Strengthening governance in pharmaceutical systems: a compendium of case studies.* Submitted to USAID by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. https://siapsprogram.org/wp-content/uploads/2018/03/18-054-SIAPS-GovCase-Study-Compendium_FINAL.pdf

- WHO. (2022). *Managing conflicts of interest, a how-to guide for public pharmaceutical-sector committees in low- and middle-income countries.* https://www.who.int/publications/i/item/9789240057982

Capacity development is NOT training

4 PATHWAYS NEEDED TO OPTIMIZE WORKFORCE PERFORMANCE

Staffing	Skills	Working Conds.	Motivation
All critical positions and/or competencies are filled	Staff apply their skills as appropriate at every level	Working conditions support performance	Workers are motivated to do their jobs

Staffing: The ability to recruit quality candidates; Adequate pool of workers; Sufficient budget

Skills: Adequate technical & managerial competencies; Staff have leadership skills; Understand roles & responsibilities

Working Conds.: Favorable social and emotional environment; Physical environment is safe, clean and conducive to performance; Up-to-date, relevant tools and equipment

Motivation: Good performance supported; Workers have a sense of ownership of their role; SC workers understand and care about their role in the healthcare system

MTaPS' Approach to E-Learning

- Increasing acceptance and use of digital approaches

  – Need for digital competence (digital competence for health workers)

  – Wider use of technology for e-learning
- Importance of instructional design
- Application of adult learning principles
- Competency-based approach
- Using a variety of interactive methods
- Ensure integration and sustainability for ongoing use

Have you considered 'Curriculum curatorship'?
Use your learning objectives and your assessment but use learning materials that other people have created.

MTaPS has created a range of e-learning courses that you can use…

MTaPS Open Access E-learning Materials

Course Title	Overview of Course	Number of Modules	Link
Pharmaceutical Systems Strengthening (PSS) 101	Overview of PSS, including strengthening quality assurance systems, combating antimicrobial resistance, pharmaceutical sector governance, and logistics for health commodities	10 modules	https://www.globalhealthlearning.org/program/pharmaceutical-systems-strengthening
Good Governance in the Management of Medicines	Importance of good governance in pharmaceutical management, including key interventions to promote good governance and considerations for implementing improvement strategies	8 modules	https://www.globalhealthlearning.org/course/good-governance-management-medicines
Antimicrobial Resistance (Part 1)	Basic principles of antimicrobial resistance, including its impact on individuals and society	3 modules	https://www.globalhealthlearning.org/course/antimicrobial-resistance-part-1-0
Antimicrobial Resistance (Part 2)	Contributing factors to development and spread of antimicrobial resistance, including interventions to address these factors	6 modules	https://www.globalhealthlearning.org/course/antimicrobial-resistance-part-2
Pharmacovigilance	Overview of pharmacovigilance, including quality defects, medication errors, causality assessment, active surveillance methods, risk management, and data management	3 modules	https://elearning.rwandafda.gov.rw:8080/elearning/login/index.php

Why Instructional Design Matters: A Case Study

E-learning materials must be integrated into the learning culture and process of the Ministry of Health for them to be used and maintained.

Learning Management Systems need to be properly supported to be sustainable.

- **Tanzania** – Training of trainers pool, focal point trained, uploaded to Ministry of Health, Learning Management System, continuing professional development accreditation
- **Kenya** – Infection prevention and control training embedded in professional associations
- **Burkina Faso** and **Mali** – E-learning platforms hosted on government websites and trained managers managing

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Source: VectorStock

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