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Impact of Medical Products Regulation on Health Care Supply Chains

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Theme

Enhancing the delivery of good quality pharmaceutical services and products in the context of global challenge of the COVID-19

Presentation Outline

- What is medical product regulation?
- Overview of Healthcare Supply Chains
- Impact of medical product regulations on Healthcare Supply Chains
- USAID MTaPS support to countries
- Regulatory support for Covid-19
- Conclusion and take away messages

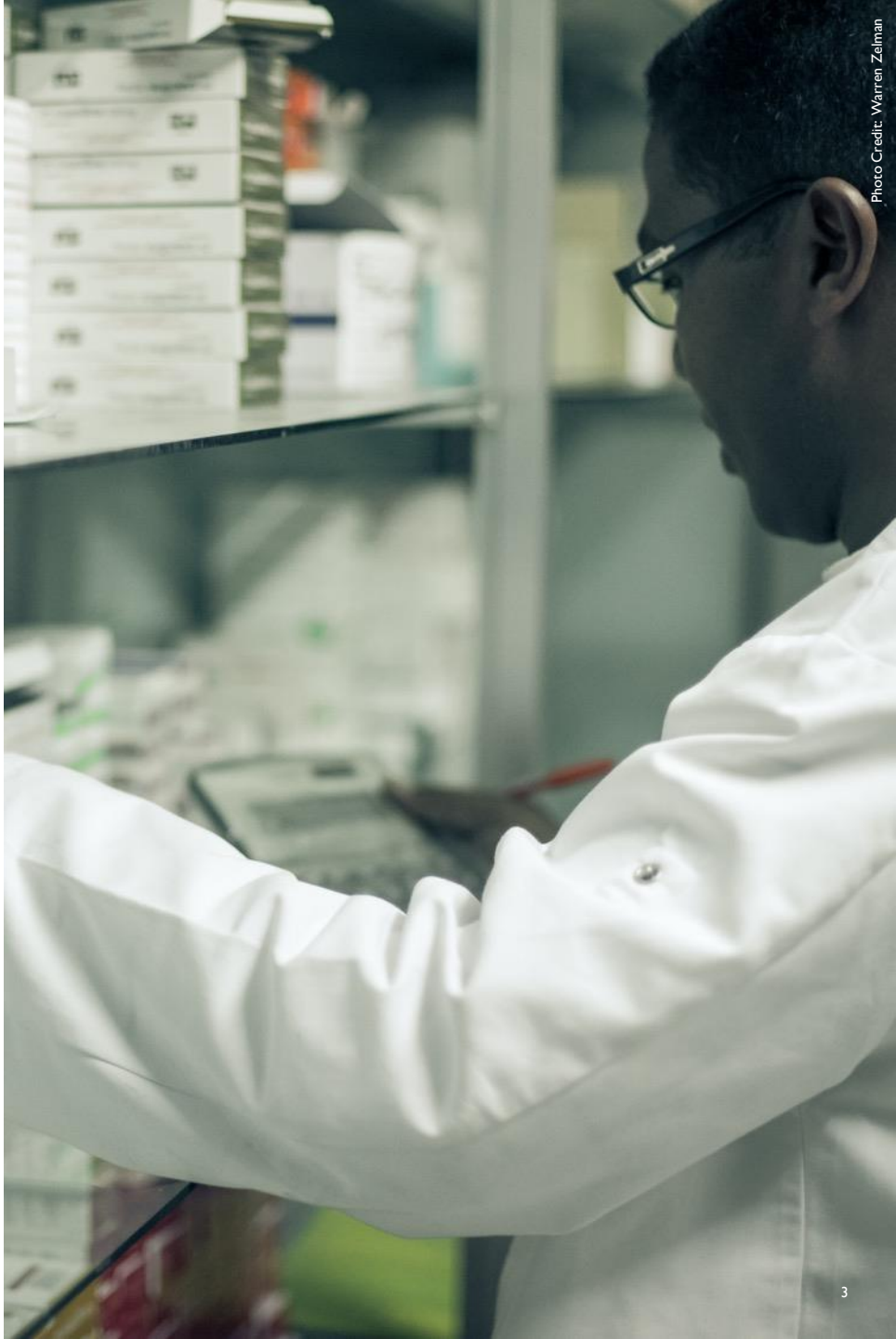
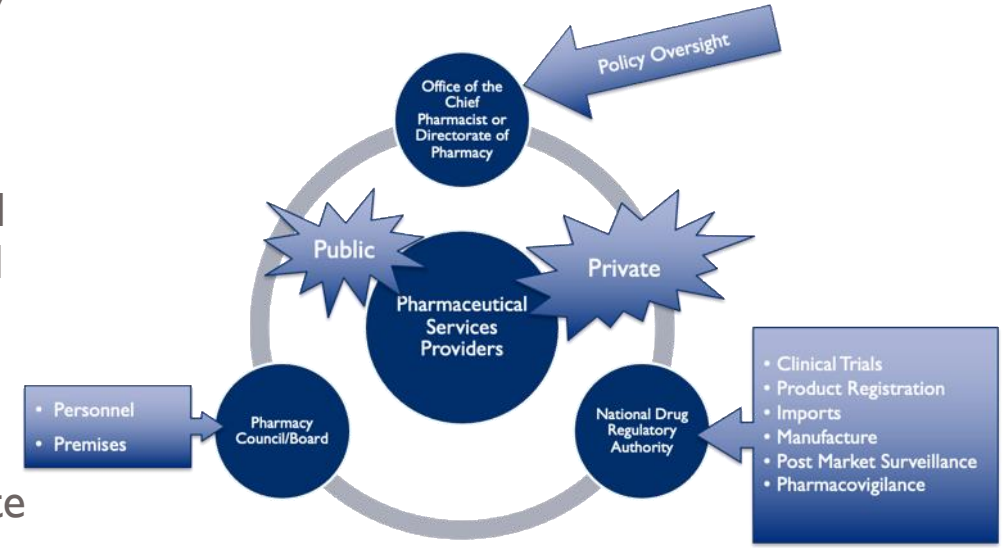


Photo Credit: Warren Zelman

What Is Medical Products Regulation?

Administrative and Technical Arrangements Made by a Government to Ensure:

- All **premises** (e.g. manufacturers, pharmacies), **persons** (e.g. quality managers within manufacturing facilities, prescribers, dispensers) and **practices** (e.g. distribution, dispensing) comply with approved standards, norms, procedures, and legal requirements
- Safe, effective, and quality-assured **medical products**
- Unbiased, accurate, and appropriate **product information**
- **Appropriate use** of medical products



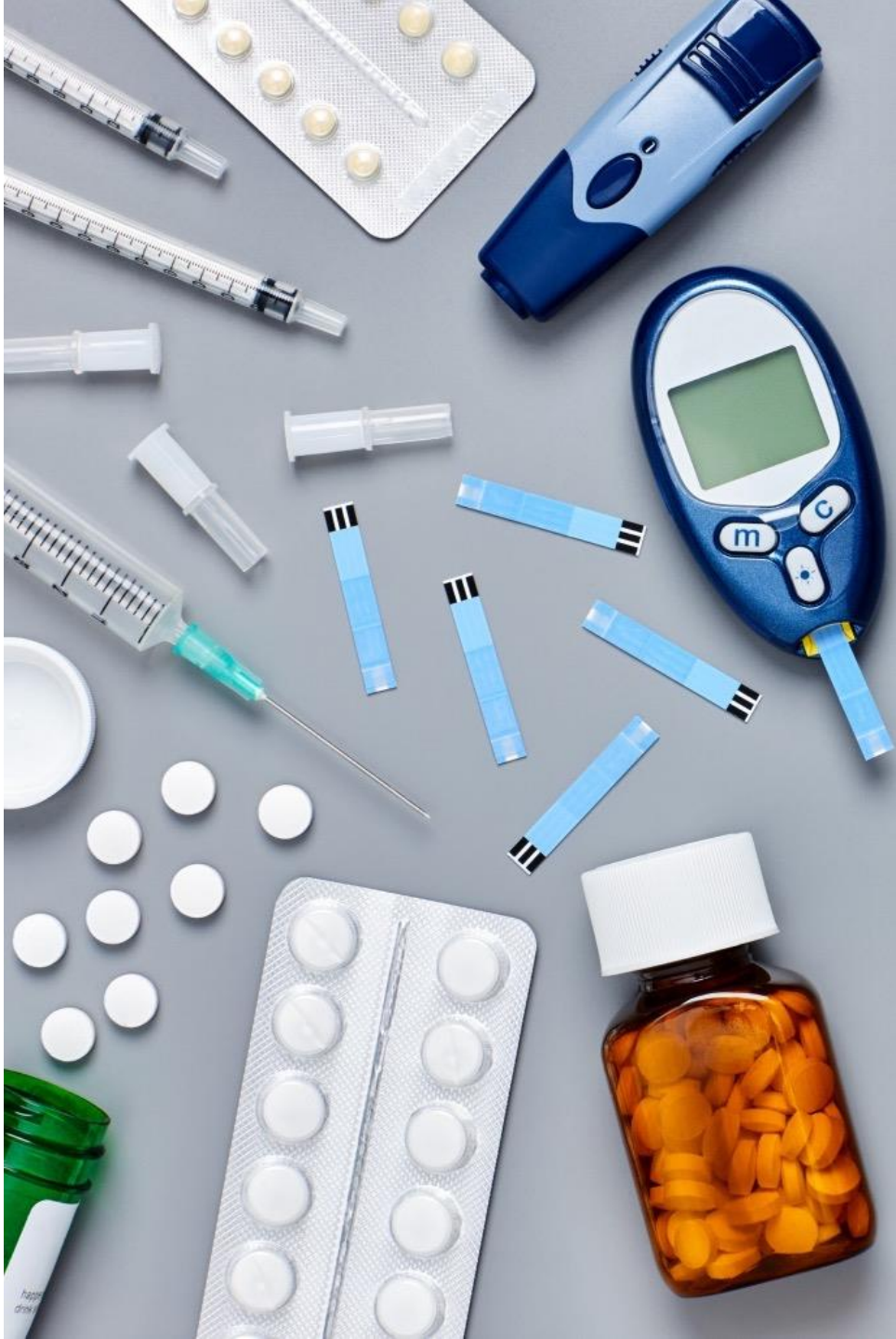
Source: UNESCAP 2009

Medical Products Regulation: Key Features

Safety

Efficacy

Quality



Regulation Along The Medical Product Life Cycle

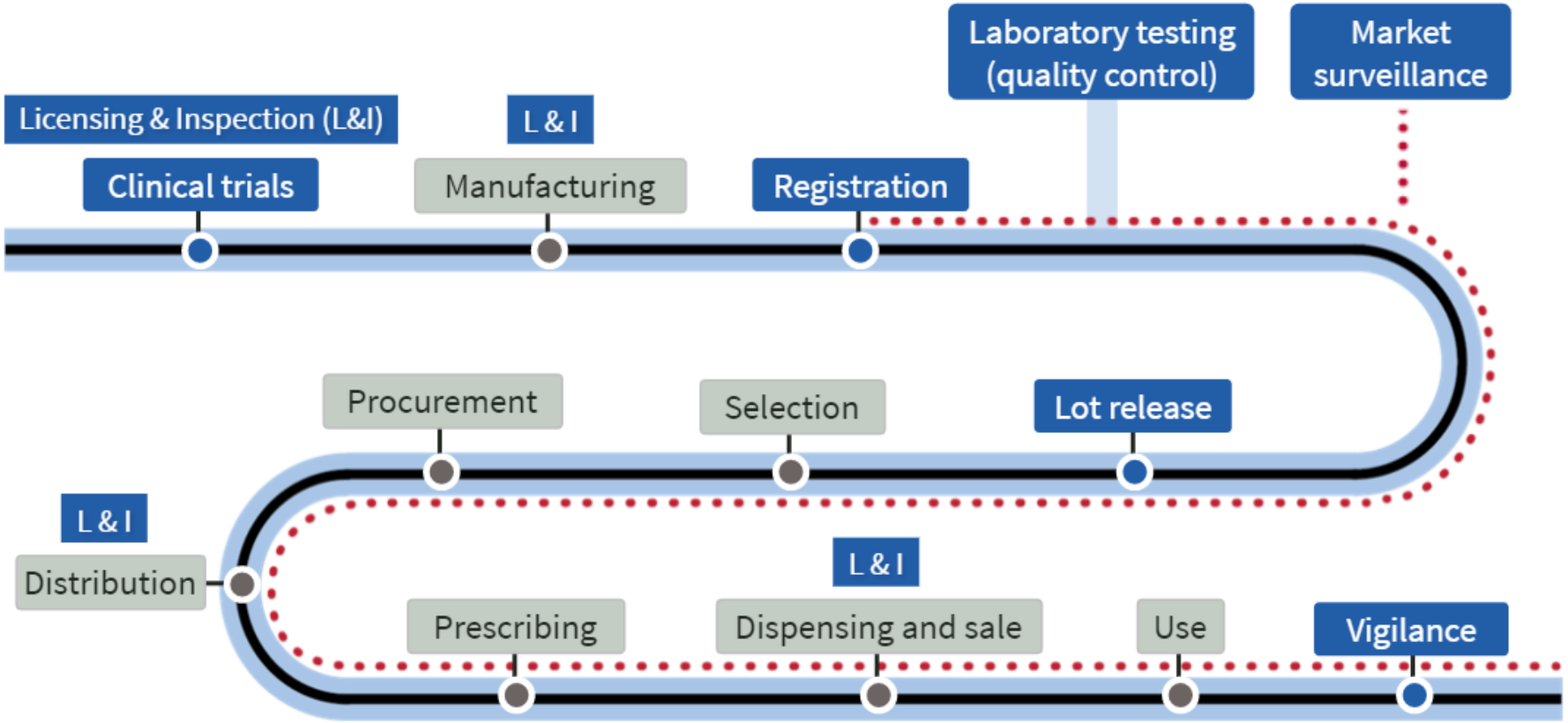
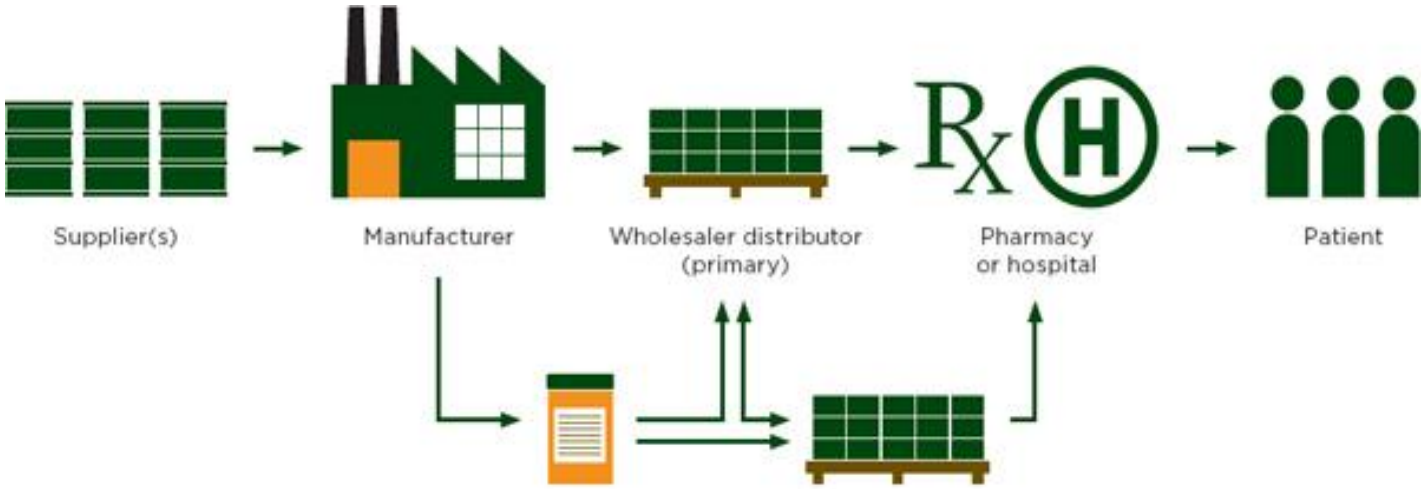
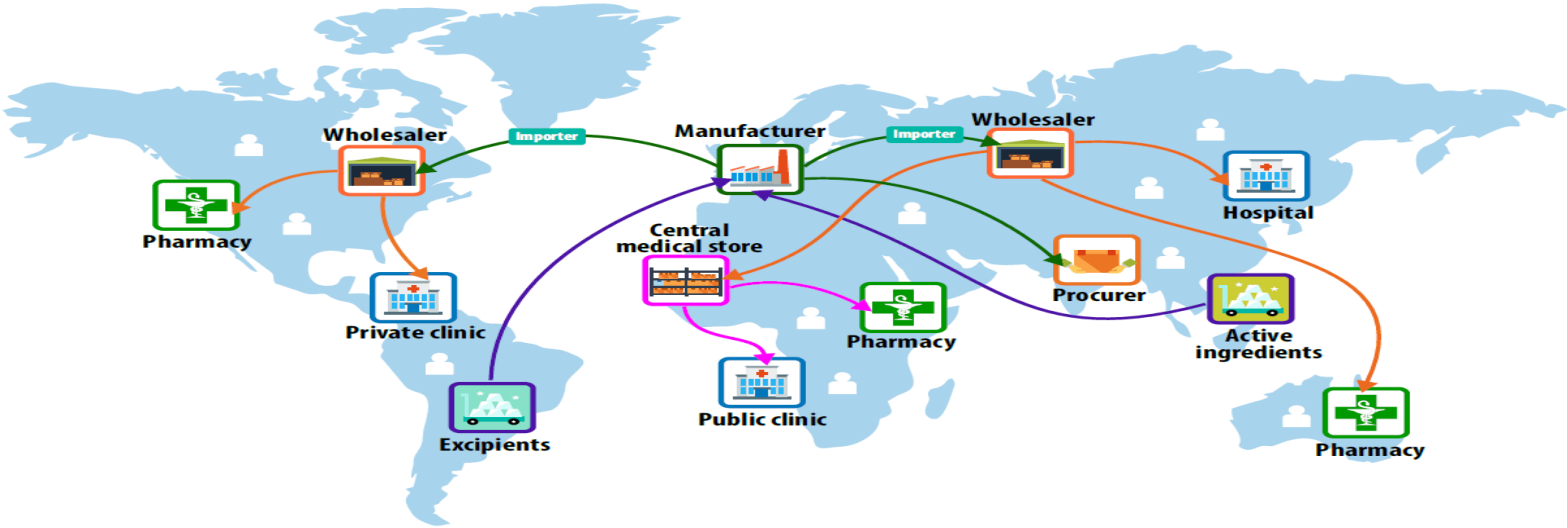


Diagram based on concepts from: *The Many Faces of Corruption: Tracking Vulnerabilities at the Sector Level (page 35) and WHO Good Governance for Medicines Programme: an innovative approach to prevent corruption in the pharmaceutical sector (page 5).*

Healthcare Supply Chain is Complex





Positive Impact of Regulation on Health Supply Chain

- Protect and promote public health by
  - Ensuring minimum standards on safety, efficacy and quality
  - Preventing suspect or illegitimate drugs (e.g., falsified or diverted medicines) from getting to consumers
- Maintain security of the supply chain from manufacturer to end user

Potential Challenges

- Shortages
  - Barriers to entry
  - Manufacturing interruptions and closures
- Low resourced national medicines regulatory authorities with limited enforcement capacity
  - Infiltration of falsified products in the supply chain
  - Uneven competition (price vs quality)

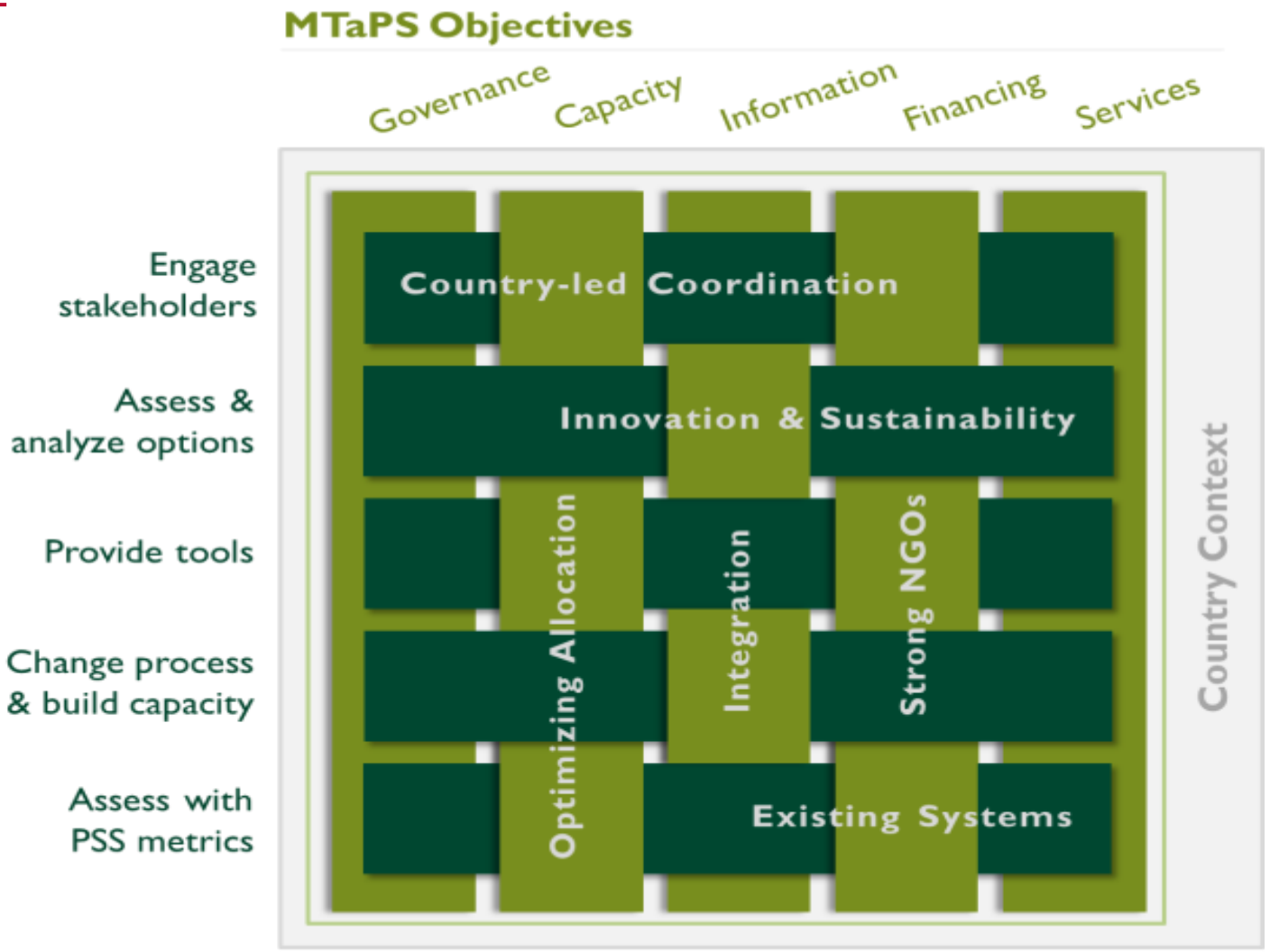
USAID MTaPS RSS Support to Countries

MTaPS' Objectives

1. Pharmaceutical-sector governance strengthened
2. Institutional and human resource capacity for pharmaceutical management and services increased, including regulation of medical products
3. Availability and use of pharmaceutical information for decision making increased and global learning agenda advanced
4. Pharmaceutical-sector financing, including resource allocation and use, optimized
5. Pharmaceutical services, including product availability and patient-centered care to achieve desired health outcomes, improved

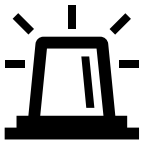
PHOTO CREDIT: WARREN ZELMAN

MTaPS' Approach to Strengthening Pharmaceutical Systems



Regulatory Support To Countries

Adopt model pharmaceutical legislation, policies, guidelines, and norms



Establish mechanisms to ensure oversight and enforcement of policies, laws, and regulations

Develop NMRAs' institutional capacity

Improve PV systems

Design active surveillance systems for new medicines

Support behavior change interventions for providers and patients

Photo Credit: Fabrice Duhal

Regulatory Support for Covid-19 Vaccine Introduction

COVID-19 Vaccine Introduction

MTaPS' Technical Areas of Assistance

1. **Evidence-based policy, coordination, and planning**
   Support the country in assessing, planning and decision-making to develop National Deployment Vaccination Plan.

2. **Financing strategy**
   Map financing sources, determine gaps, and help develop a financing strategy.

3. **Regulatory support for vaccines and supplies**
   Work with regulatory authorities to rapidly introduce quality-assured vaccines and related equipment and supplies.

4. **Procurement and supply chain management**
   Help develop quick and responsive supply chain solutions that factor in cold chain requirements to preserve vaccine stability.

5. **Patient safety surveillance following immunization**
   Assist with establishing or adapting national pharmacovigilance system to monitor patient safety post-immunization.

6. **Advocacy and social mobilization**
   Help develop a communications strategy, advocacy materials, and local partnerships to engage communities, address concerns, and prevent the spread of misinformation.

7. **Monitoring and evaluation**
   Develop a vaccine introduction results framework and monitoring plan that will reflect the needs of the country.

Regulatory Support For Vaccines & Supplies

- Work with regulatory authorities to rapidly introduce quality-assured vaccines and related equipment and supplies:
  - Expedited emergency use authorization & registration
  - Facilitation of bilateral deals and imports
  - Alignment of medicine and pharmacy laws & regulations
  - Requirements and processes for safety monitoring

Vaccine Service Delivery and Patient Safety

- Define approaches, provide immunization services and set up active patient safety monitoring:
  - Pharmacovigilance regulations and guidelines
  - Enhanced spontaneous reporting for tracking adverse reactions to vaccines
  - Active surveillance systems for adverse events of special interest
  - AEFI causality analysis, decision making & communication
  - Tracking adherence to immunization protocols

Conclusion and Take Away Messages

- Regulation strives to promote and protect public health
- Regulatory systems should have inbuilt mechanisms to respond to public health emergencies such as Covid-19 pandemic
- Failures in regulation could lead to serious consequences in endangering the life and health of patients, shortages and price fluctuations
- Health supply chains are complex and require clear regulations and guidelines to ensure safe and quality assured products reach the end user

Useful Resources and References

- MTaPS Website: www.mtapsprogram.org
- WHO Regulatory Updates on Covid -19: https://www.who.int/teams/regulation-prequalification/covid-19
- Victoria R. Green, Agata Dabrowska, Kate M. Costin, FDA's Role in the Medical Product Supply Chain and Considerations During COVID-19, R46507, September 1, 2020 accessed 02/09/2021, https://crsreports.congress.gov/product/pdf/R/R46507

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Thank You

FOR MORE INFORMATION

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