Promoting the Quality of Medicines Plus

Promoting Medical Product Quality Assurance to Achieve Better Health Outcomes

Webinar: HSS Learning Series

December 18, 2023

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Promoting the Quality of Medicines Plus

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Impacts Extend Beyond Health

Promoting the **Quality** of **Medicines** Plus

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Today's Discussion Topics

How does systems thinking build sustainability?

Jude Nwokike, Vice President, U.S. Pharmacopeia (USP)

Director, Promoting the Quality of Medicines Plus (PQM+) program

What is the link between service delivery and quality-assured medicines?

Neimatu Adjabui, Principal Program Manager, West Africa, PQM+, USP

What is the burden of substandard and falsified (SF) medical products on the health system?

Edward Abwao, Sr. Tech. Advisor, Regulatory Systems Strengthening, PQM+,USP

Achievement of Global Health Priorities

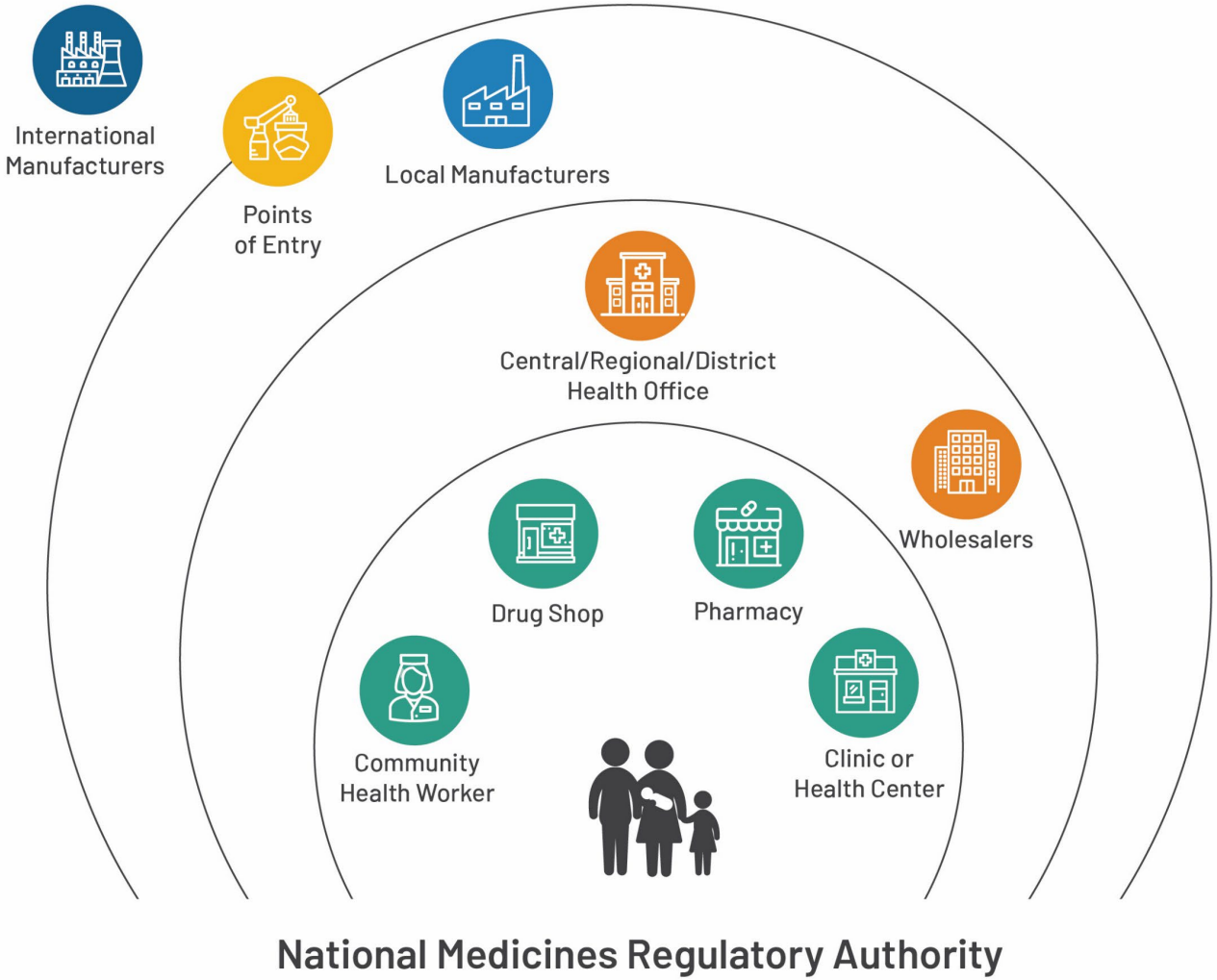
- Sustainable Development Goal 3: “Ensure healthy lives and promote well-being for all at all ages…”
- Target 3.8: “Achieve universal health coverage, including financial risk protection, access to quality essential health care services and **access to safe, effective, quality, and affordable essential medicines and vaccines for all**.”
- USAID adapts and interprets the three main components of the UHC goal as achieving population equity in health outcomes through implementation of high-quality interventions and optimization of all health-sector resources.

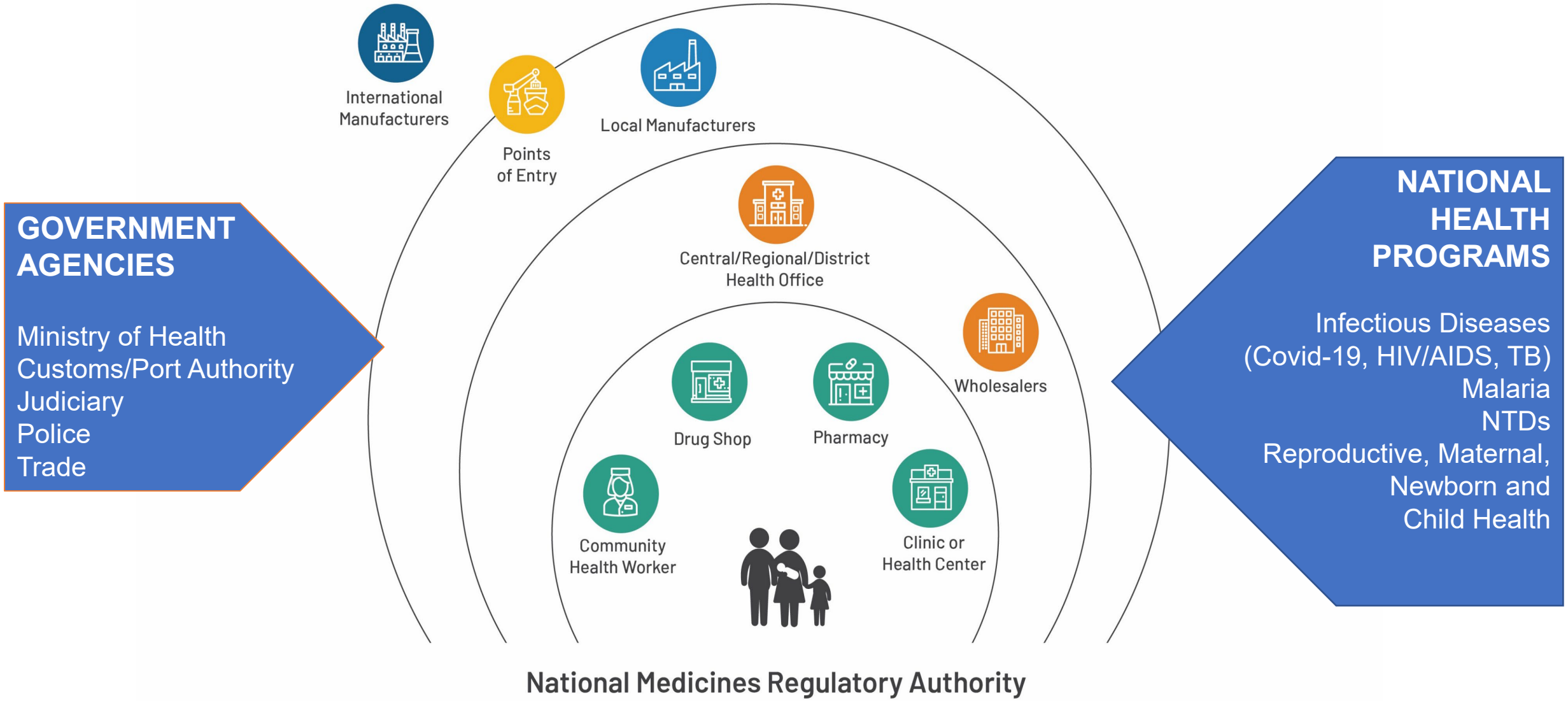
Why do all countries need a strong medical product regulatory system?

- **Health and well-being** of patients, families, communities, and populations
- **High-market value** makes the pharmaceutical sector especially vulnerable to corruption, waste, and mismanagement
- **Consumers do not have the necessary information** about quality or when, how, or which medicines to use
- **The large number of stakeholders** involved increases opportunity for quality to be compromised
- **Premises, practices, and people** must follow quality standards
- **Supply chains can compromise the quality of medical products** during storage and distribution
- If poor-quality medical products are found, effective **recall, removal, and disposal mechanisms** must be in place

Source: Rago et al 2008

Medical Product Quality Assurance SYSTEM




GOVERNMENT AGENCIES
Ministry of Health
Customs/Port Authority
Judiciary
Police
Trade
International Manufacturers
Points of Entry
Local Manufacturers
Central/Regional/District Health Office
Wholesalers
Drug Shop
Pharmacy
Community Health Worker
Clinic or Health Center
National Medicines Regulatory Authority
NATIONAL HEALTH PROGRAMS
Infectious Diseases (Covid-19, HIV/AIDS, TB)
Malaria
NTDs
Reproductive, Maternal, Newborn and Child Health

Mentimeter Poll

Three ways to join:

1. Scan the QR code with your smartphone.

2. Follow the link in the chat.

3. Go to menti.com and type in the code: **66627714.**

Nine Regulatory Functions

1. National Regulatory System
2. Registration and Market Authorization
3. Vigilance
4. Market Surveillance and Control
5. Licensing Establishments
6. Regulatory Inspection
7. Laboratory Testing
8. Clinical Trials Oversight
9. NRA Lot Release

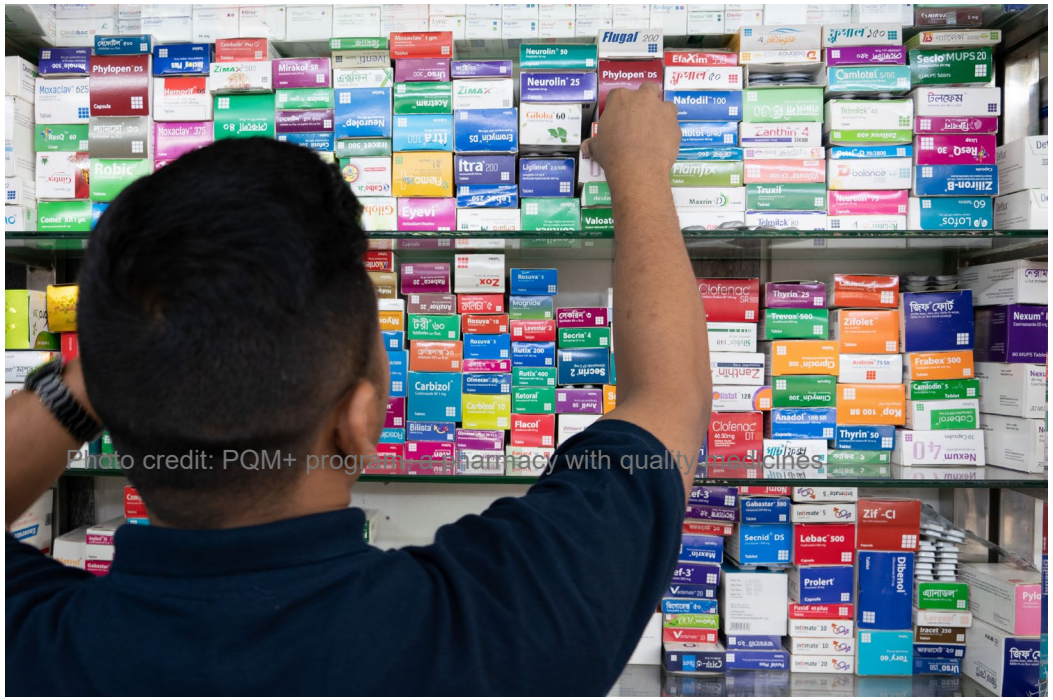


Photo credit: PQM+ program | Pharmacy with quality medicines

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Systems Thinking Builds Sustainability

Jude Nwokike

Vice President, USP

Director, PQM+ Program

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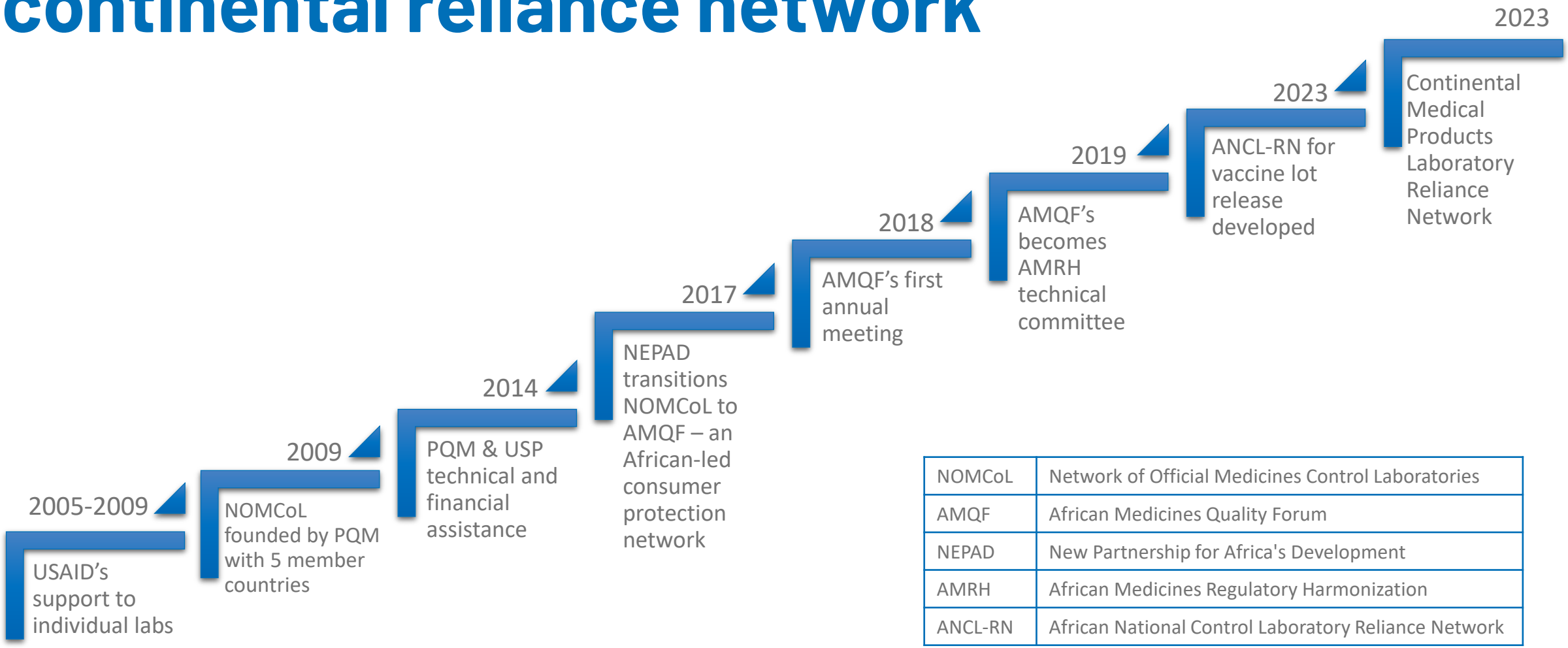
Early USAID investment pays off in a continental reliance network



NOMCoL	Network of Official Medicines Control Laboratories
AMQF	African Medicines Quality Forum
NEPAD	New Partnership for Africa's Development
AMRH	African Medicines Regulatory Harmonization
ANCL-RN	African National Control Laboratory Reliance Network

Decade of support helps Pakistan meet local needs, contributes to regional investigation

*DRAP – Drug Regulatory Authority of Pakistan

Promoting the Quality of Medicines Plus

Service delivery and quality-assured medicines

Neimatu Adjabui

Principal Program Manager, West Africa, PQM+, USP

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Understanding the Link to Service Delivery

- Support national regulatory authorities (NRAs) to protect public health by ensuring the delivery and use of quality-assured medical products through:
  - Strengthening the market surveillance and control function
  - Building lab capacity to enhance detection of substandard and falsified (SF) medicines

Photo credit: PQM+ program, building lab capacity in Ghana

Why does this matter?

- A well-functioning NRA has the ability to detect SF medicines and take action to save lives.
- SF medicines can contribute to mortality and morbidity.
- Need to ensure distribution and delivery of quality-assured medicines at point-of-care.
- By detecting and responding to remove/prevent their circulation, NRAs can contribute to reducing morbidity and mortality.

Strengthening market surveillance and control to check quality along supply chain

- Support to Benin to strengthen import control
- Support to Ghana and Mali to strengthen their market control systems and conduct risk-based post-marketing surveillance of antimalaria and MCH medicines.
- NRAs in both countries detected SFs with higher SFs for MCH medicines
- Detection led to regulatory actions to protect public health

Photo credit: PQM+ program, Risk-based post marketing surveillance in Ghana

What was the impact in these countries?

- Overall changes:
  - *Amplification of national and global dialogue/strategies*
  - *Swifter regulatory actions*
  - *Local production of oxytocin*
  - *Quality survey of oxytocin in other countries*

- Ghana enforcement actions
  - *Circular issuance for storage*
  - *Fines*
  - *Seizures*
  - *Recalls*
  - *Withdrawal of medical authorization*
- Mali's enforcement actions
  - *Recalls*
  - *Quarantining*
  - *Sensitization*

Building Lab Capacity to Enhance Detection of SF Medicines

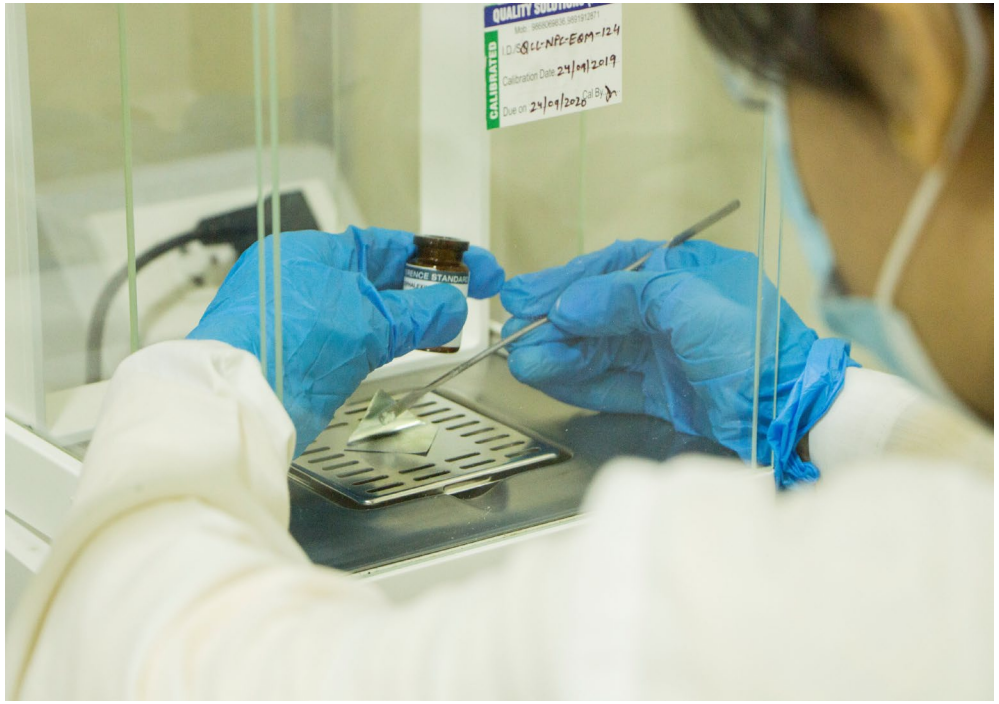

Photo credit: PQM+ program, medicines quality testing in a lab

- Lab Testing and Control is a vital component of regulatory systems strengthening (RSS) and one of the nine WHO Global Benchmarking Tool (GBT) regulatory functions.
- National quality control laboratories (NQCLs) should be able to conduct comprehensive tests and have a quality management system (QMS) that supports the reliability of test results
- By helping to detect SF medical products and remove them from circulation, **NQCLs help to save lives.**

What was the impact?

Photo credit: PQM+ program, testing lab in Mali

Mali

- Achieved the international standard - ISO/IEC 17025 accreditation - for 4 lab techniques and submitted dossier for scope expansion for another 4 techniques.
- To sustain this progress: Mali has a new 5-year strategic plan and a resource mobilization plan to facilitate sustainability.

Burkina Faso

- Ability to conduct full compendial testing.
- Submitted dossier for ISO/IEC 17025 accreditation.
- To sustain this progress: new 5-year strategic, business and communications plans developed; already started mobilizing resources to sustain and maintain its ability to support the NRA.

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Modeling the Burden of Substandard and Falsified Oxytocin in Kenya

Edward Abwao, Senior Technical Advisor, Regulatory Systems Strengthening

PQM+, USP

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Introduction: Why a Model?

- SF medicines are on the market in every country. [1]
- An estimated 1 out of 10 tested samples are SF in low and middle-income countries (LMICs) [2]
- But WHO also estimates the true burden to be likely much greater.
- Countries do not know the burden of SF medicines.
- As countries better understand the burden, they will be able to make informed choices about investing to improve medicine quality.

1. Substandard and falsified medical products. Geneva: World Health Organization; 2018.
2. A study on the public health and socioeconomic impact of substandard and falsified medical products. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO.

USAID funded PQM+ to develop a tool for countries to estimate the health and economic burden of any specific SF medical product. The model estimates two major classes of outcomes.

Health outcomes:

- Life-years
- Disability-adjusted life years (DALYs)
- Quality-adjusted life-years (QALYs)
- Disease-specific outcomes

Economic/societal outcomes:

- Cost of retreatment
- Value of lost productivity from failed treatment or complications from treatment

Pilot in Kenya: Oxytocin to Treat Postpartum Hemorrhage (PPH)

Photo credit: USAID Africa/Flikr

- Core group: Karim Wanga (head of post-market surveillance for Pharmacy & Poisons Board) and PQM+
- Larger working group included representatives from:
  - Ministry of Health
  - Kenya Medical Research Institute
  - Nairobi Metropolitan Services
  - University of Nairobi
- Piloted the model in FY2022

Basic Assumptions

- The model estimated the burden of SF oxytocin in Kenya for an annual cohort of approximately 1.6 million pregnant women.
- The model used a 7% prevalence of SF medicines - the midpoint between the two extremes of the range of recent quality testing of oxytocin in Kenya.
- This model assumes the SF oxytocin has 75 – 89% of the required active pharmaceutical ingredient (API), leading to a 30% reduction in efficacy.

Results

The model estimates that, due to use of SF oxytocin in Kenya each year, there are:

Additional cases of mild PPH	2,005
Additional cases of severe PPH	489
Additional hysterectomies	26
Additional deaths	26
Life-years lost	420

Results

Estimated economic burden from use of SF oxytocin in Kenya for one year is:

Health system	$937,000
Productivity losses	$302,000
- From missed days of work	($22,000)
- From premature death	(280,000)
Total Economic Costs	**$1.24 Million**

Conclusions

- The burden of SF oxytocin in Kenya is substantial. This burden is just for one medicine. What is the likely burden of using SF versions of the many other essential medicines in the market in Kenya?

- Kenyan parliamentarians were concerned about these results and want to explore further.

What's next?

- The model can be used by any country to estimate the burden of SF medicines in its market.
- A version focused on SF antibiotics to treat childhood pneumonia has also been developed.

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Questions & Discussion

Visit www.usp-pqmplus.org

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Closing Remarks

Alison Collins, MBA/MA
Health Systems Advisor
Office of Health Systems, USAID

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2024 USAID HSS Learning Series – Call for Webinar Ideas

- In 2024, USAID is opening up participation in the HSS Learning Series to the wider health system strengthening community
- An initial call for webinar ideas for 2024 went out on December 4th
- If you have a webinar idea that you would like to present as part of this series, please reach out to HSSlearning@usaid.gov for more information.

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Thank you and happy holidays!

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