



Medicines Quality Assurance Systems Strengthening Program (MQASSP)

Applicants' Conference

December 13, 2018

Office of Health Systems

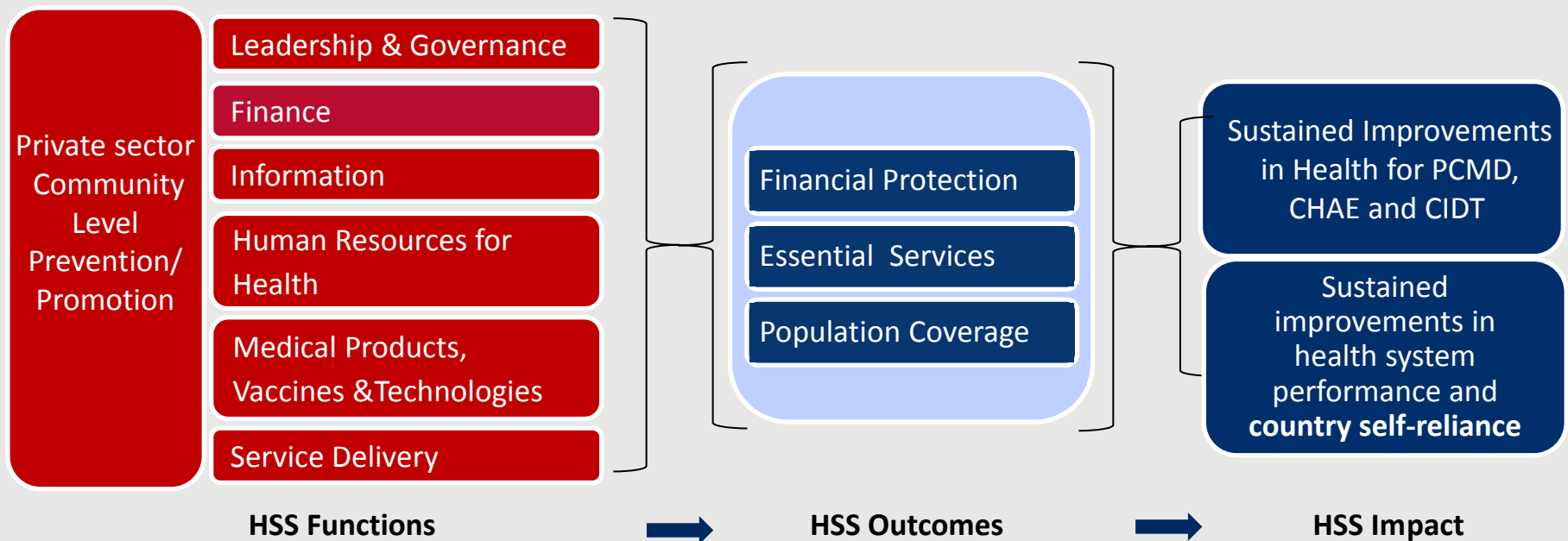
Bureau for Global Health

AGENDA

- 9 – 9:30 am: Registration
- 9:30 – 10:30 am: Applicants' Conference Presentations
 - Welcome and Background - *Kelly Saldana*
 - MQASSP Vision – *Alison Collins*
 - Eligibility and Timelines – *Boryana Boncheva*
 - Q&A Session – *Moderated by Boryana Boncheva*
 - Closing Remarks – *Alison Collins*
- 10:30 – 12 pm: Networking Session

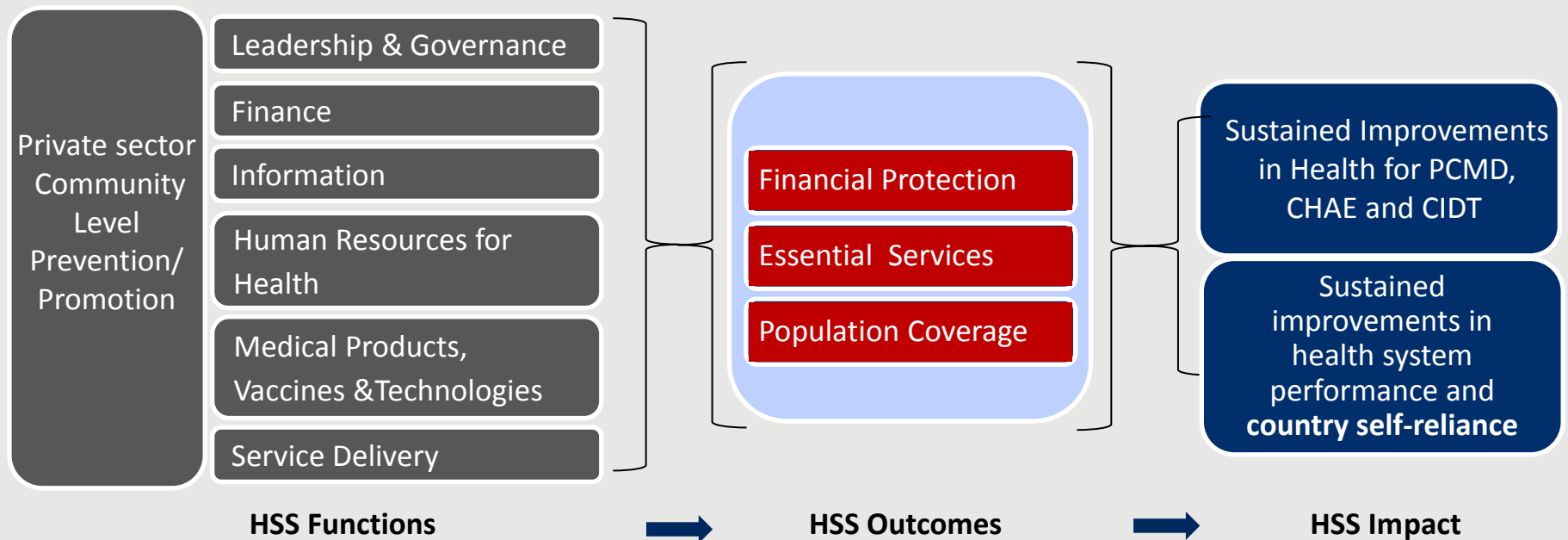
Health Systems: A Changing Focus

From Core Functions to Outcomes



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From Core Functions to Outcomes



Integrated Health Systems Improvement Program (IHSIP)

Awards and Funding – 2018-2024

HSS Outcomes

HSS Accelerator

IHS IDIQ

(unrestricted pool and small business set aside)

**Medicines Quality Assurance System
Strengthening Program (MQASSP)**

**Medicines, Technologies, and
Pharmaceutical Services (MTaPS)**

Human Resources for Health 2030

Financial Protection

Cost of accessing services does not
impoverish or curb necessary care

Essential Services

Capacity to deliver an essential package of
high-quality services to those who need it

Population Coverage

Equity-focused access to services for poor
and marginalized

Grants/Cooperative Agreements

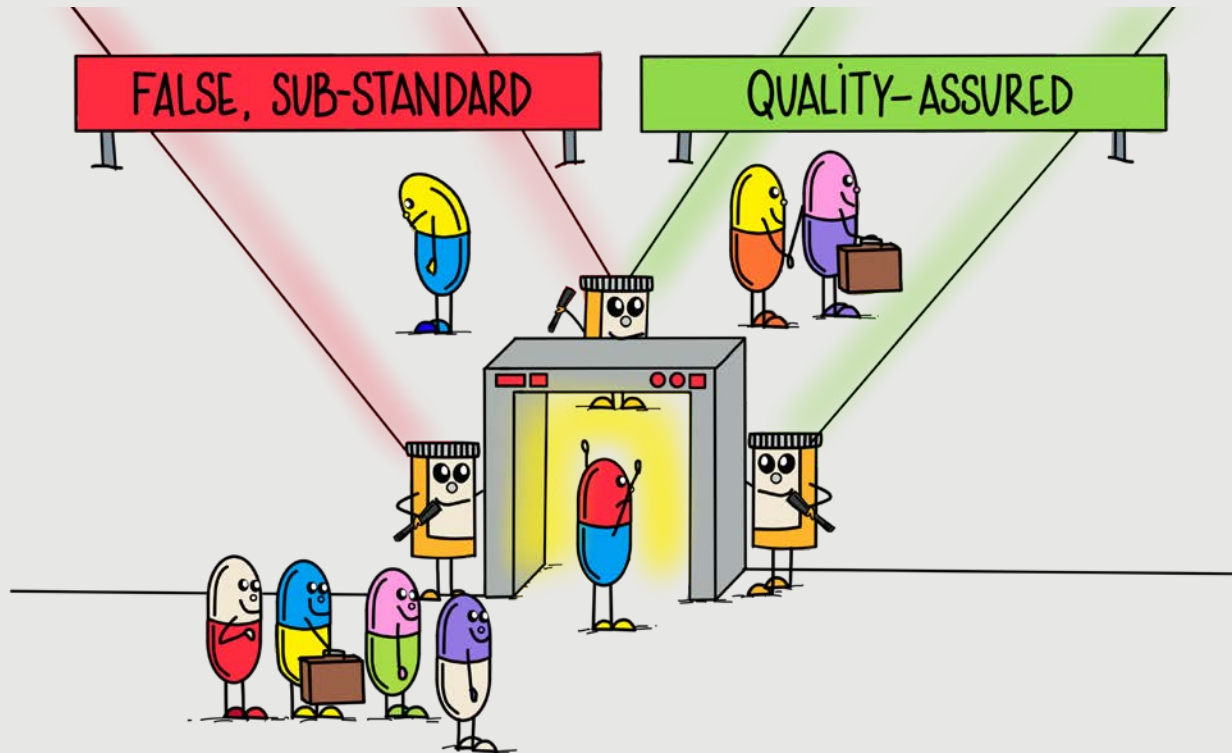
Contracts

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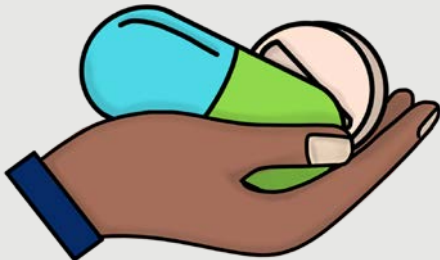
MQASSP Overview

- **GOAL:** Sustainably strengthen medical product quality assurance systems in LMICs



Improving governance for medical product quality assurance systems

- Evidence-based medical product quality assurance legislation, regulations, and policies to support both country and regional efforts
- Systems that facilitate transparency and accountability
- Linkages between the medical product quality assurance system and other sectors
- Coordination across entities (public and private) with medical product quality assurance responsibilities



Strengthening country and regional **regulatory systems**



- Market authorization/registration, inspection, and licensing functions of medical product regulatory agencies
- Sustainable post-marketing surveillance systems that enable appropriate regulatory action
- Medicines quality control laboratory capacity
- Regional harmonization initiatives to strengthen regulatory capacity and networks



- Information systems integrated and data standards adopted to support regulatory medical product quality assurance functions
- Expanded medicines regulatory and quality assurance workforce

Improving **allocation and use** of financial resources

- Availability of additional and sustainable resources, for example:
 - Cost recovery (e.g., fees)
 - Domestic resource mobilization
- Support for optimal prioritization/use of investments for quality assurance systems strengthening, for example:
 - As informed by the WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory system
 - Using risk-based approaches

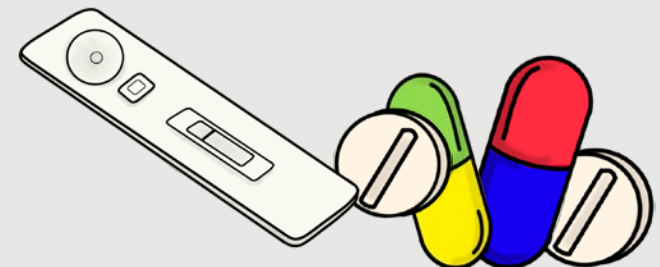


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Increasing supply of quality-assured medical products

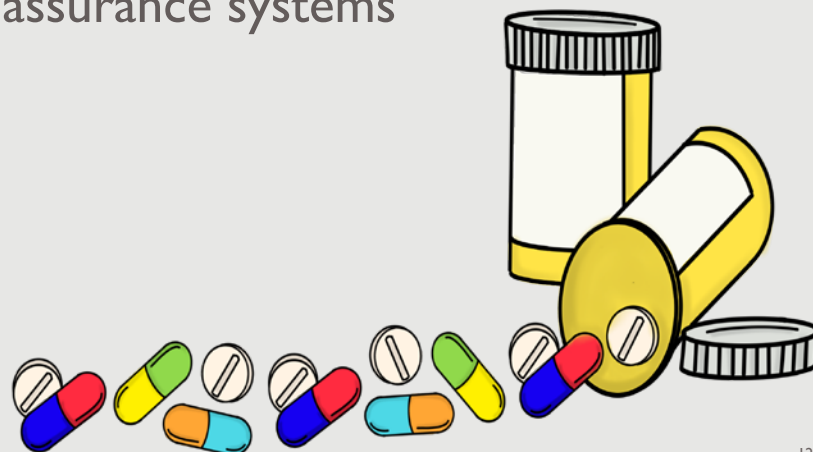


- Support for Good Manufacturing Practices (GMP) and product regulatory submissions/dossiers
- Systems for market intelligence and analytics of the public health pharmaceutical market
- Capacity of local contract research organizations (CROs) to conduct bioequivalence studies for dossier submissions
- Health coverage schemes incorporate medical product quality requirements



Advancing the global agenda for medical product quality assurance

- Evidence-based approaches and tools developed and/or applied
 - Including product quality screening technologies and their application in LMICs
- Advocacy on the importance of medicines quality assurance for public health
 - Including the link between medical product quality and antimicrobial resistance
- Research and analysis to support quality assurance systems strengthening



MQASSP Timeline

June 6, 2018
RFI posted

Dec. 13, 2018
Applicant's
Conference

June 2019
Anticipated award of
PQM+

Nov. 15, 2018
USAID Business
Forecast
Announcement

January 2019
Anticipated APS Solicitation
release date
Including Window 1: PQM+

June 2019
Anticipated posting of
Window 2: iMQA

MQASSP mechanisms will build on the success of the Promoting the Quality of Medicines (PQM) program

- Information on PQM can be accessed at:
 - PQM website (www.usp-pqm.org)
 - Development Experience Clearinghouse (DEC) (<https://dec.usaid.gov/dec/home/Default.aspx>)
- Information on MQASSP
 - RFI posting (<https://www.grants.gov/web/grants/view-opportunity.html?oppld=306011>)
 - Applicants Conference information

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THANK YOU!

Please send questions to ihsip@usaid.gov

