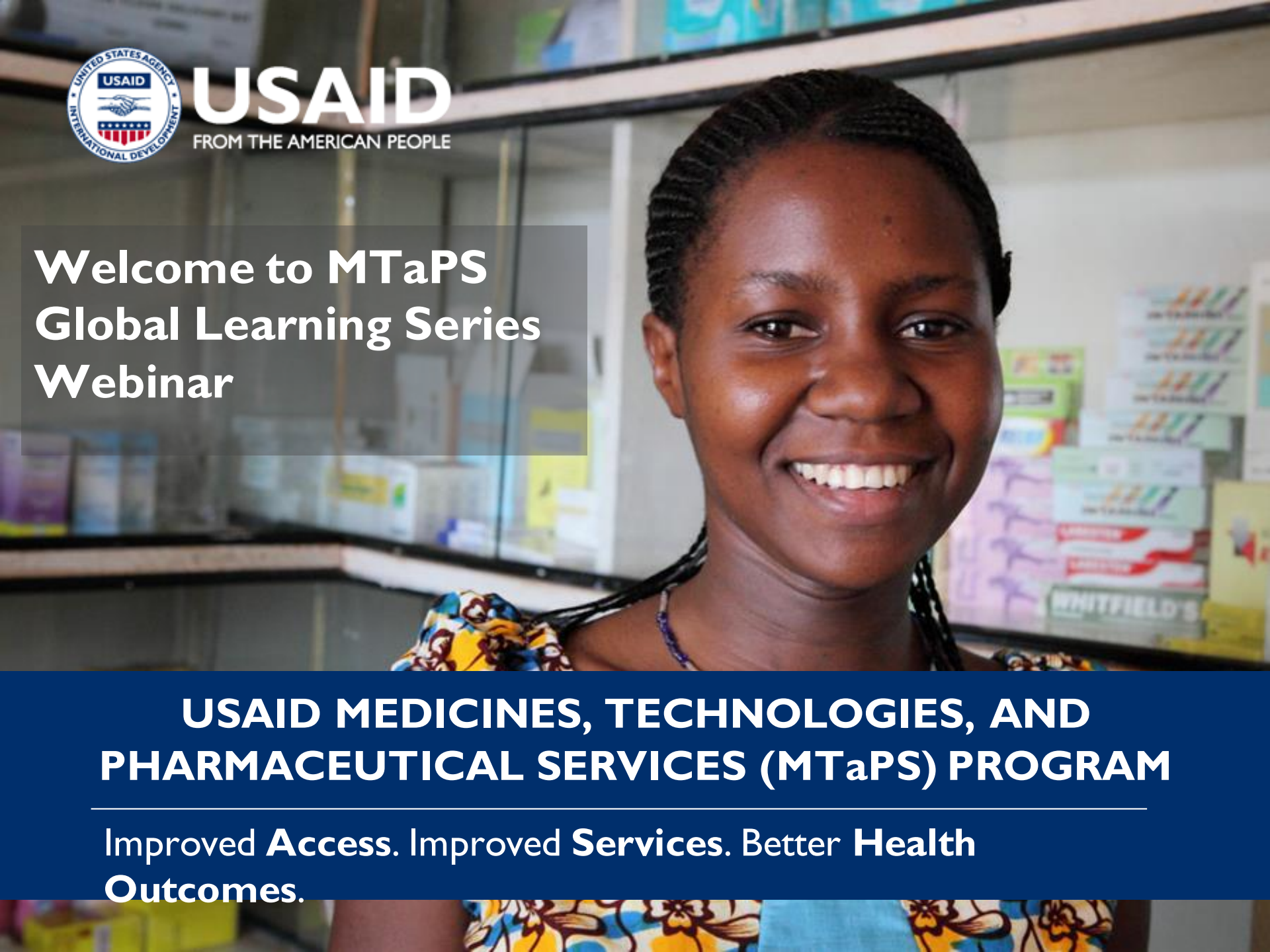

USAID
FROM THE AMERICAN PEOPLE
Welcome to MTaPS Global Learning Series Webinar
USAID MEDICINES, TECHNOLOGIES, AND PHARMACEUTICAL SERVICES (MTaPS) PROGRAM
Improved **Access**. Improved **Services**. Better **Health Outcomes**.

USAID MEDICINES, TECHNOLOGIES, AND PHARMACEUTICAL SERVICES (MTaPS) PROGRAM

Improved Access. Improved Services. Better Health Outcomes.

MTaPS GLOBAL LEARNING SERIES WEBINAR

Medicines to Markets: Building Effective Medicines Registration Systems in LMICs

April 13, 2021

Photo credit: Abimana Rwandenzi Eugene, MTaPS Rwanda

USAID
FROM THE AMERICAN PEOPLE

Welcome and Agenda

Javier Guzman
Technical Director
MTaPS

USAID
FROM THE AMERICAN PEOPLE

AGENDA

- Opening Remarks, USAID
- Global Context for Regulatory Systems Strengthening, WHO
- Building Stronger Medicines Registration Systems in LMICs, MTaPS
  - Overview
  - Bangladesh
  - Mozambique
  - Nepal
  - Rwanda
- Partnering with the Private Sector, IFPMA*
- Q&A
- Closing Remarks

*IFPMA - International Federation of Pharmaceutical Manufacturers and Associations

Photo Credit: Warren Zelman

Opening Remarks

Alexis Leonard
USAID Contracting Officer's Representative (COR) Lead, MTaPS Program
Senior Health Systems Technical Advisor
USAID Office of Health Systems

USAID
FROM THE AMERICAN PEOPLE

Global Context of Regulatory Systems Strengthening (RSS)

World Health Organization

Hiiti Sillo

Team Lead, Regulatory Systems Strengthening

Regulation and Safety Unit

Regulation and Prequalification Department, WHO

Objectives of the WHO Regulatory System Strengthening Programme

1. Build regulatory capacity in Member States consistent with good regulatory practices
2. Promote regulatory cooperation, convergence and transparency through networking, work-sharing and reliance

Source: WHO RSS team

Mandate & Importance

- **WHA Resolution 67.20 (2014)**

  ✓ Recognizes the importance of strong regulatory systems to a well-functioning healthcare system and the attainment of health-related SDGs and UHC

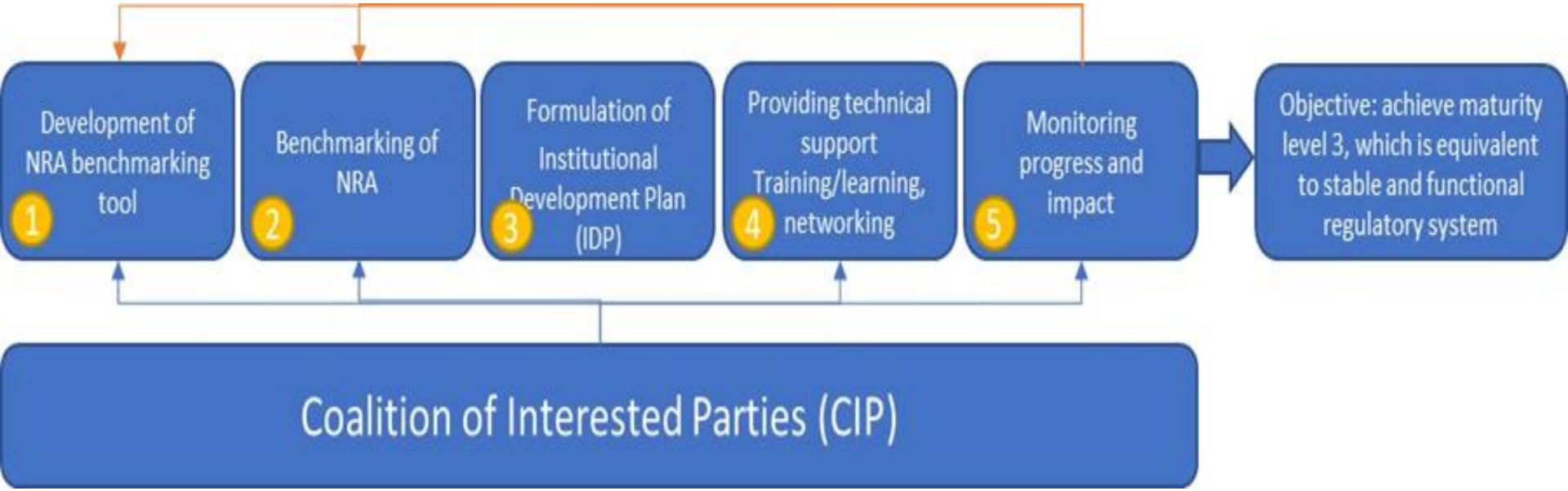
- **SDG 3 – Target 3.8**

  ✓ 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

Source: WHO RSS team

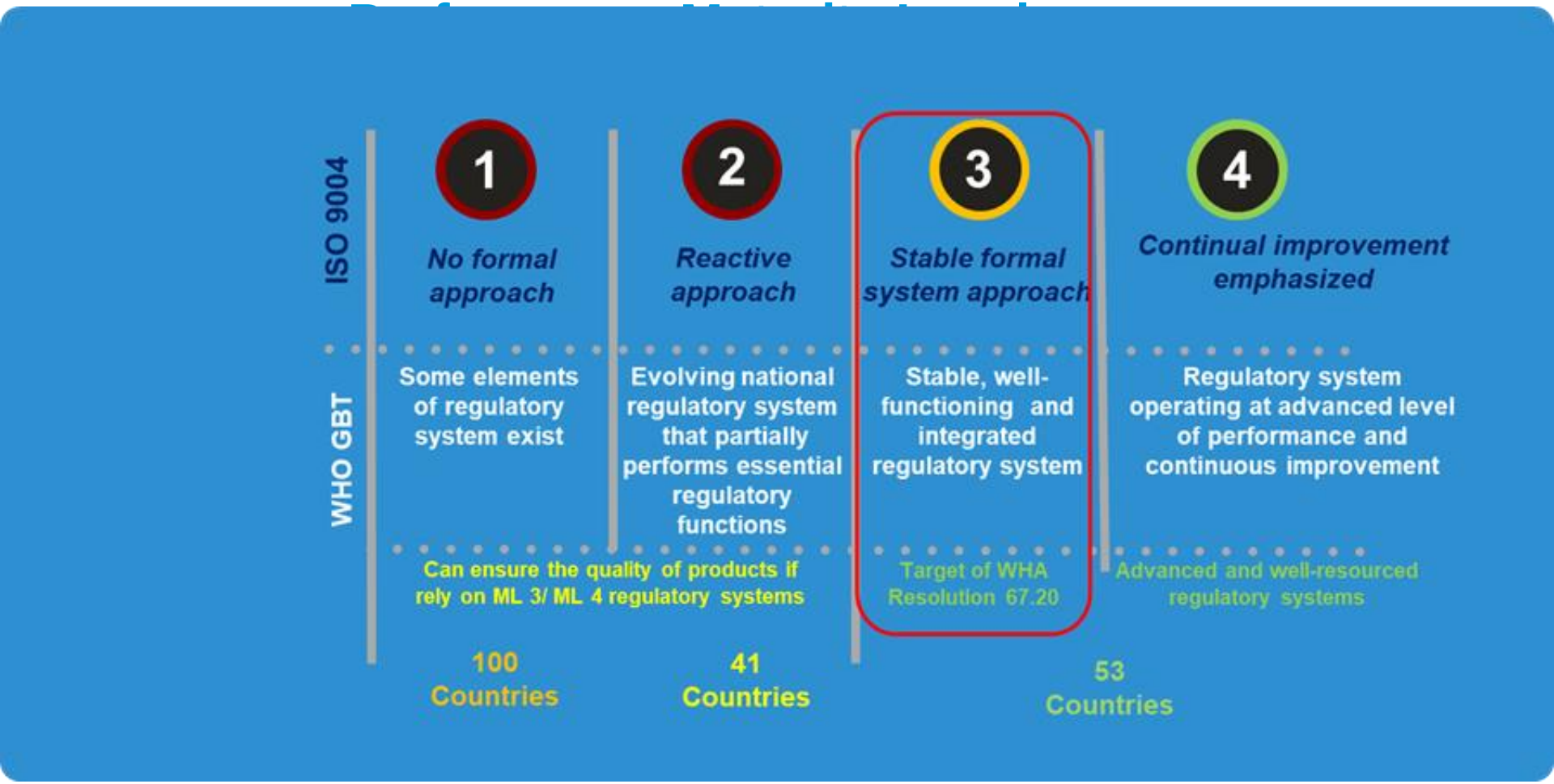
WHO Five-Step Capacity Building Model for National Regulatory Authorities (NRAs)

As per Resolution WHA 67.20 on Regulatory Systems Strengthening (2014)



Source: WHO RSS team

WHO Global Benchmarking Tool (GBT)



Source: WHO RSS team

Purpose and Objectives of the CIP Network

A framework for collaboration between the WHO and participants in the CIP Network:

- ✓ establish and promote a **unified strategic** and **coordinated approach** to strengthening national and regional regulatory systems
- ✓ contribute to the implementation of Resolution WHA 67.20, as well as the common objectives of the CIP participants
- ✓ increase the effectiveness of **collective efforts** and **desired impact** in countries and regions

Goal: Help countries achieve a **stable, well-functioning regulatory system** (GBT Maturity Level 3)

Status: Voluntary collaborative mechanism – according to WHO's rules, regulations, policies and procedures, including a Framework for Non-State Actors (FENSA)

- ➢ Excellent pilots in Bangladesh, Nepal and Rwanda with Parties such as USAID MTaPS, PQM+, and others
- ➢ Collaboration in benchmarking and IDP (Institutional Development Plan) implementation

CIP: Coalition of Interested Parties

Source: WHO RSS team


THANK YOU
World Health Organization

USAID MEDICINES, TECHNOLOGIES, AND PHARMACEUTICAL SERVICES (MTaPS) PROGRAM

Improved Access. Improved Services. Better Health Outcomes.

Building Strong Medicines Registration Systems in LMICs

Kate Kikule
Principal Technical Advisor
Regulatory Systems Strengthening
MTaPS

USAID
FROM THE AMERICAN PEOPLE

Outline

- Key features of medical products regulation
- Significance of product registration
- Elements of an effective medicines registration system
- Challenges in the establishment of robust registration systems
- MTaPS' strategic approach to building strong registration systems
- Overview of MTaPS Technical Assistance to countries

Key Features of Medical Products Regulation

- Safety
- Efficacy
- Quality

Regulation Along the Medical Product Life Cycle

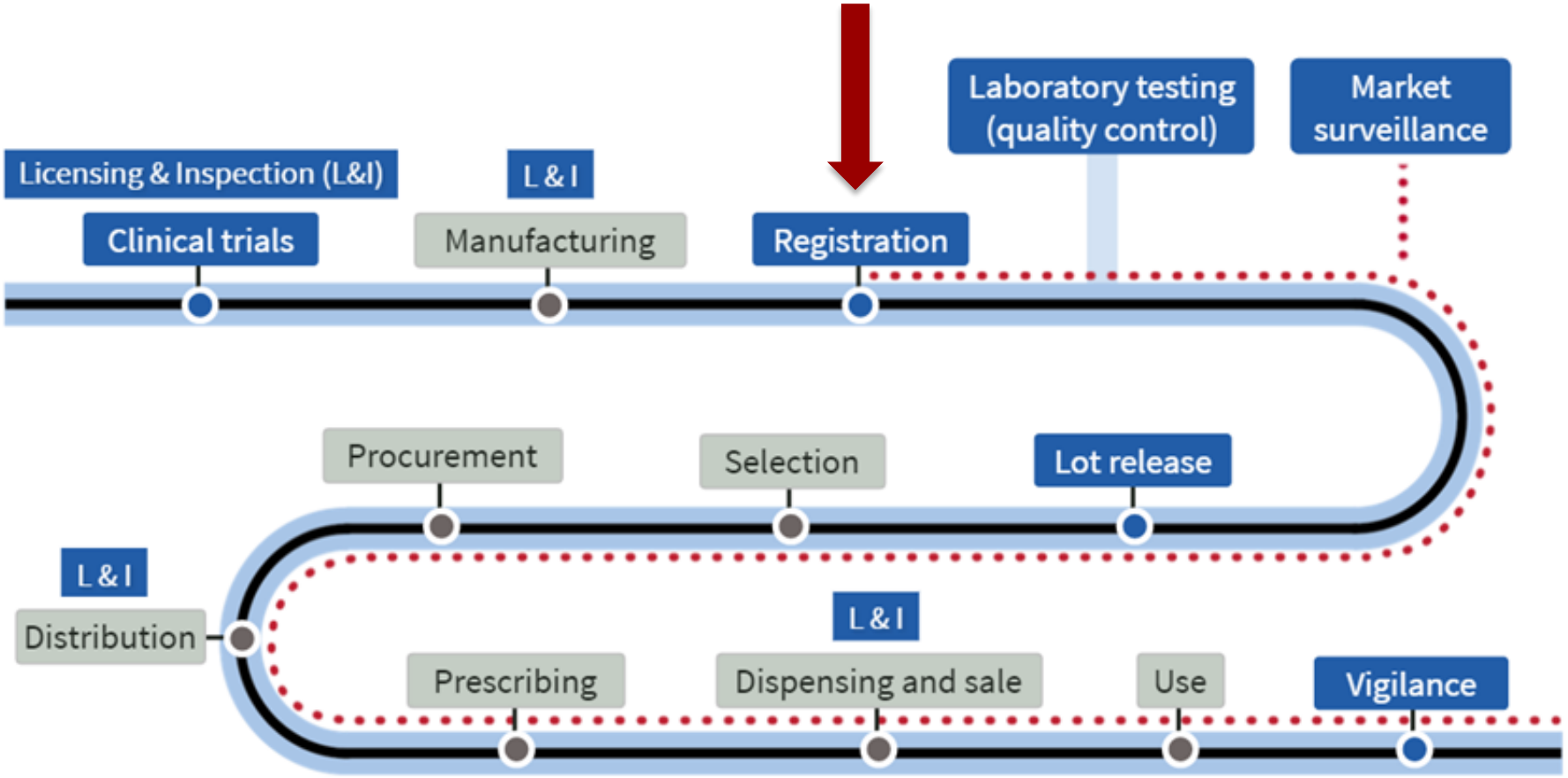


Diagram based on concepts from: *The Many Faces of Corruption: Tracking Vulnerabilities at the Sector Level (page 35) and WHO Good Governance for Medicines Programme: an innovative approach to prevent corruption in the pharmaceutical sector (page 5).*

Registration/Marketing Authorization: What Is It and Why Is It Important?

Objective: To provide a system which ensures that only medical products that have been authorized by the national regulatory authority are allowed to be manufactured, imported, distributed, sold or supplied.

- Procedure for approval of a product for marketing by reviewing data on quality, safety, and efficacy
- Same standards should be applied to imported and locally manufactured products
- Countries greatly benefit from using reliance mechanisms

Elements of an Effective Registration System

Key Elements*

- Legal and regulatory framework
- Organization and good governance
- Human resource capacity
- Quality management system
- Transparency, accountability, and communication
- Performance monitoring and evaluation

Other Elements

- Digitization of the registration process
- Infrastructure
- Financial resources

** WHO Global Benchmarking Tool (GBT)*

Establishment of Strong Registration Systems: Common Challenges

- Lengthy process to revise and update the legal and regulatory framework
  - Guidelines and registration procedures
- Changes in leadership in the NMRAs
- Inadequate technical workforce to conduct product assessments
- Context of public health emergencies (COVID-19 pandemic)

  - Total time to registration in some LMICs could average 4-7 years
  - Is there any provision for regulatory reliance and flexibility? (e.g., US FDA and WHO Prequalification Scheme)

MTaPS RSS Strategic Approach (1)

Conduct NMRA Assessments	Promote good governance	Strengthen legal and regulatory framework	Implement quality management system
➢ Consensus with leadership / management of the NMRA ➢ Use of the WHO GBT ➢ Development of Institutional Development Plan ➢ Implementation with prioritization and options analysis	➢ Establishing governance structure depts. or divisions responsible for registration of medicines ➢ Defining organization and structure ➢ Establishing/updating job descriptions ➢ Establishing functional technical committees	➢ Development and establishment of legal provisions, regulations, and guidelines ➢ Promote convergence, harmonization, and reliance	➢ Documentation and implementation of QMS (ISO 9001:2015 certification, development, and review of SOPs)

MTaPS RSS Strategic Approach (2)

Develop human resource capacity	Implement Good Review Practices (GRevP)	Install electronic management information systems
➢ Basic/advanced specialized training ➢ Establish/roll-out training policy and programs ➢ Develop training methodologies	➢ Assist establishment of GRevP principles ➢ Conduct reviews ➢ Assist establishment of project management processes/tools	➢ Provide customized solutions ➢ Implement and roll-out use of Pharmadex

MTaPS Technical Assistance (1)

- **Conducting of NMRA Assessment using the WHO GBT**
- **Promotion of good governance**

Nepal

- **Implementation of the Institutional Development Plan (IDP)**
- **Strengthening legal and regulatory framework**

Bangladesh, Mozambique, Nepal, and Rwanda

MTaPS Technical Assistance (2)

- **Documentation and implementation of QMS**

  Mozambique, Nepal, Philippines, and Rwanda

- **Capacity building to improve knowledge and skill set for evaluation of product dossiers**

  Bangladesh, Mozambique, and Rwanda

- **Deployment of electronic information management systems**

  Pharmadex: Bangladesh, Mozambique, Nepal

  Support to existing software: Rwanda (PRIMS)

MTaPS: Support to Countries

USAID MEDICINES, TECHNOLOGIES, AND PHARMACEUTICAL SERVICES (MTaPS) PROGRAM

Improved Access. Improved Services. Better Health Outcomes.

Strengthening Medicines Registration System in Bangladesh

Jebun Rahman
Country Project Director
MTaPS Bangladesh

USAID
FROM THE AMERICAN PEOPLE

What We Found in Bangladesh

- Limited financial autonomy of DGDA
- Outdated requirements for renewal and variations of product registration
- No recognition by DGDA of registration decisions & inspections of reference NRAs
- BAPI members hesitant toward WHO-prequalified medical products
- Low HR capacity
- Lack of standardized registration processes
- Weak electronic drug assessment procedures

DGDA: Directorate General of Drug Administration
BAPI: Bangladesh Association of Pharmaceutical Industries

What We Did in Bangladesh: MTaPS Support to DGDA

- WHO GBT self-assessment and development of Institutional Development Plan (IDP)
- Establishment of a periodic monitoring mechanism of IDPs and its implementation
- Development of:
  - Action Plan based on DGDA's 5-year strategic plan
  - Quality management protocols as part of QMS implementation
- Capacity building: Trained assessors and industry
  - 50 DGDA inspectors and 52 people from 38 manufacturers
- Supported Industry and DGDA in the submission, evaluation, and approval of eCTD dossiers for cardiovascular drug registration
- Assisted DGDA in public consultation to adopt guidelines as per GBT, e.g., for GMP, dossier submission, and marketing authorization applications

Why It Matters to Bangladesh

- Implementation of IDPs established with DGDA as a routine to track progress
- Stronger culture of quality practice
- Both Industry & DGDA equipped with master trainers on CTD* dossier submission & evaluation
- Cardiovascular and biological products registered using CTD format. Vaccine registration's usage of CTD to follow

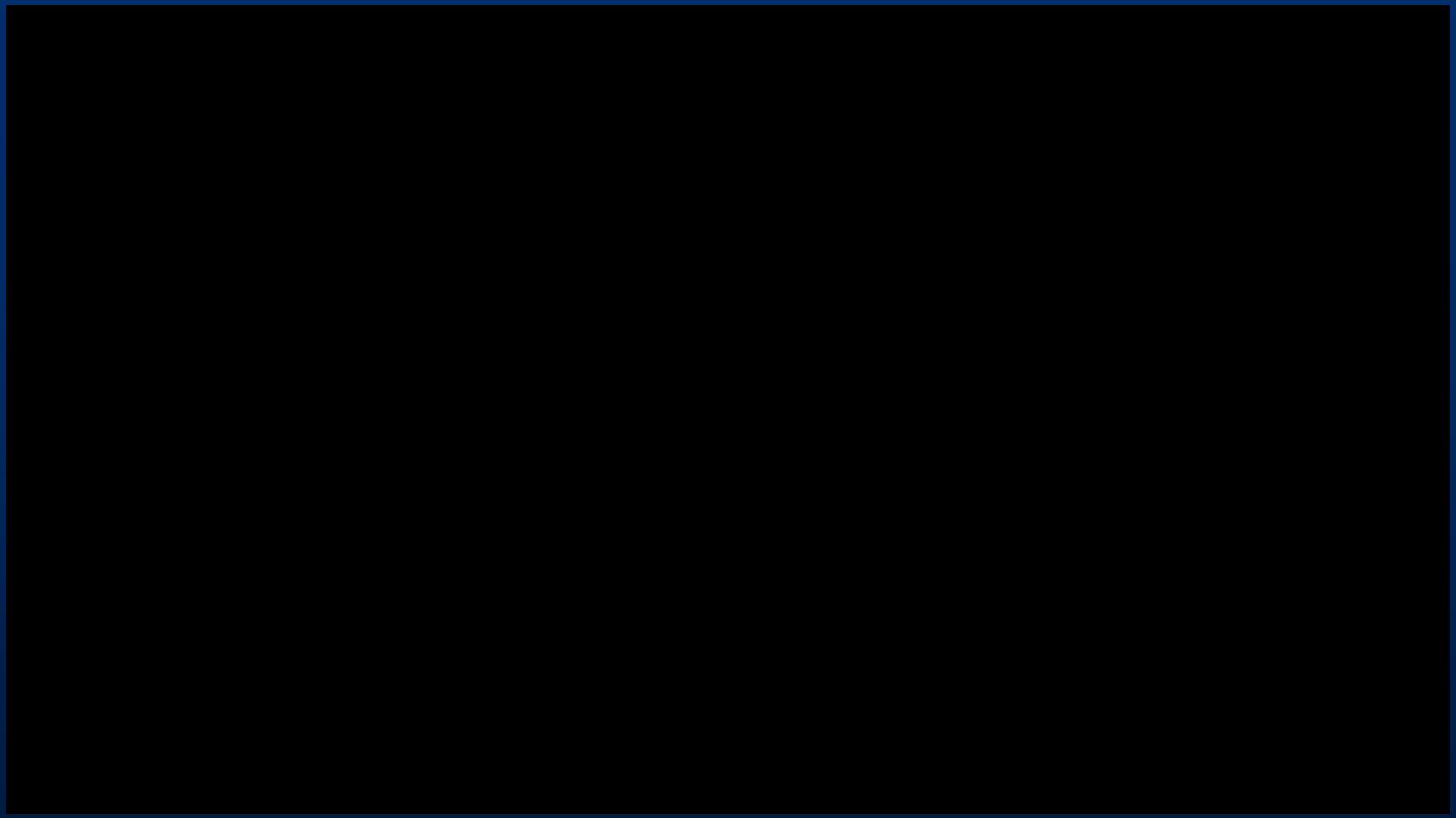
* CTD: Common Technical Document

What Next for Bangladesh

- Continuing IDPs toward GBT maturity level '3'
- Support on DGDA's 5-year strategic/action plan
- Streamlining country's registration system: guidelines/procedures/training
- Implementation of Good Review Practices focused on biologics & vaccines
- Automation of DGDA's functions (Integrated Regulatory Information Management Systems)

Testimonial from Government Partner

Maj. Gen. Md Mahbubur Rahman
Director General
Directorate General of Drug Administration (DGDA)
Bangladesh



Maj. Gen. Md Mahbubur Rahman
Director General
Directorate General of Drug Administration (DGDA), Bangladesh

USAID MEDICINES, TECHNOLOGIES, AND PHARMACEUTICAL SERVICES (MTaPS) PROGRAM

Improved Access. Improved Services. Better Health Outcomes.

Building a Stronger Medicines Registration System in Mozambique

Denylson Namburete
Country Project Lead
MTaPS Mozambique

USAID
FROM THE AMERICAN PEOPLE

What We Found in Mozambique

- Limited capacity of the National Directorate of Pharmacy (DNF*) for registration
  - Good Review Practices
  - Assessment of medical products dossiers
  - Quality Management System (QMS) for registration
- Lack of fully functional information system for registration
- Lack of regulations, guidelines, and procedures to reinforce

DNF: National Directorate of Pharmacy

What We Did in Mozambique

Focus	When	What We Did
Regulation and Guidelines for Registration	In 2020	Worked with DNF (now transformed into ANARME, the semi-autonomous National Medicines Regulatory Authority) to develop guidelines: • Guidelines on Good Review Practices • Guidelines on labelling and package leaflets for medicines
Capacity Building for Registration	In 2019	Supported DNF in hosting the 22nd Regional Joint Medicines Registration (ZAZIBONA) Assessors Meeting Supported participation of a DNF medicines registration pharmacist in the joint ZAZIBONA dossier evaluation workshop *ZAZIBONA: Botswana, Namibia, Zambia, and Zimbabwe*
	In 2020	Facilitated training of medicines assessors in Good Review Practices
Information System for Registration	In 2019	Deployed Pharmadex software to enable applicants to submit applications online
	Currently	Updating Pharmadex to meet the Common Technical Document format of product dossiers in accordance with WHO and SADC* guidelines

SADC: Southern African Development Community

Why It Matters for Mozambique

- More efficient and transparent approach in the evaluation of dossiers
- Reduced time needed to register a medicine and reduced backlog of dossiers at the DNF
- Improved compliance with GBT indicators and maturity level for marketing authorization function according to global standards
- Stronger legal framework for registration

What Next for Mozambique

- Continue implementing Pharmadex to meet the Common Technical Document format requirements of product dossiers in accordance with WHO and SADC guidelines
- Build capacity for assessment of bioequivalence studies
- Support DNF in other capacity building areas for registration, recommended by WHO GBT and IDP to ensure safety, efficacy, and quality of medical products on market

Statement from Government Partner

Dr. Velma Paul
Head of Registration Department
National Directorate of Pharmacy (DNF)
National Medicines Regulatory Authority (ANARME)
Mozambique

"MTaPS Mozambique supported the National Directorate of Pharmacy (DNF) in hosting the 22nd Regional Joint Medicines Registration (ZAZIBONA) assessors meeting held March 18-22, 2019 in Maputo.

MTaPS funded participation of an additional DNF medicines registration pharmacist to the next session of the joint ZAZIBONA dossier evaluation workshop in Botswana from June 17–22, 2019.

MTaPS provided a workshop on principles and application of Good Review Practices for medicines registration and supported the development of Good Review Practices Guidelines.

This support is an important contribution to the improvement of the DNF Medicines registration system."

- Dr. Velma Paul
Head of Registration Department
DNF/ANARME
Mozambique

USAID MEDICINES, TECHNOLOGIES, AND PHARMACEUTICAL SERVICES (MTaPS) PROGRAM

Improved Access. Improved Services. Better Health Outcomes.

Nepal: Challenges and Importance of an Effective Medicines Registration System

Dr. Birna Trap
Country Project Director
MTaPS Nepal

USAID
FROM THE AMERICAN PEOPLE

What We Found in Nepal

- Only 4 assessors – recruitment through public service commission
- Overwhelming workload
- WHO best practices only partially implemented
- Hardcopy usage and manual handling
- Poor and unreliable data quality in existing information system
- Lack of regional collaboration and harmonization
- No Quality Management System
- Very low registration fees – $27 imported / $3 local medicines

Handing in hard copy dossiers.

Assessor and manager registration Dept.

World Health Organization

Facilitators

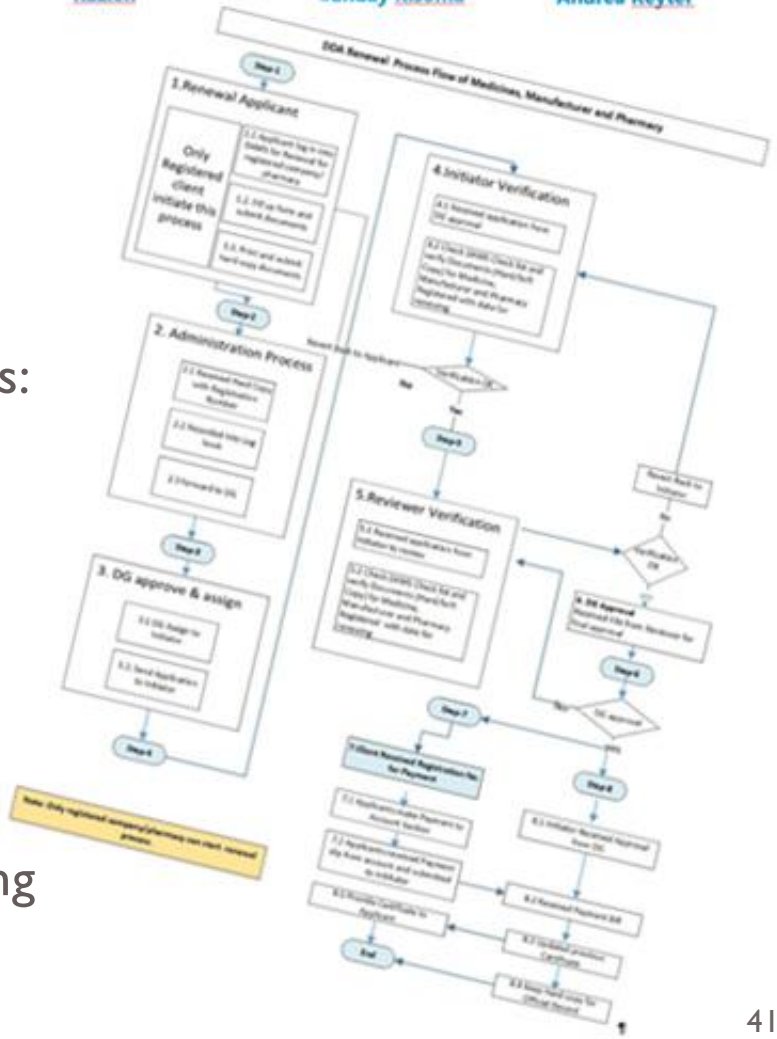

Razieh


Sunday Kisoma


Andrea Keyter

What We Did in Nepal

- Supported WHO GBT assessment
- Helped with law revision and increased renewal validity
- Reorganized and increased staffing norms
- Introduced WHO dossier review practices:
  - Implementing GBT recommendations
  - Pharmadex – revising work processes
  - Establishing registration committee
  - Building dossier review capacity
- Implemented Pharmadex to replace existing information system



Why it Matters to Nepal

- Stronger medicines regulation
- Enhanced safety, efficacy and quality of medical products
- Harmonized registration process
- Increased transparency and efficiency with better data quality and use
- Following dossier evaluation best practices
- Support for local manufacturers
- Increased availability of essential products and locally produced products
- Improved health outcomes

Photo Credits: Rabin Shrestha

What Next for Nepal

Increase GBT maturity level by:

- Law revision
- Increase staffing norms
- Reorganize
- Operationalize Pharmadex
- Revise workflow
- Orient applicants
- Introduce WHO Good Review Practices
- Capacitate assessors
- Harmonize and collaborate with SEARN
- Work toward ISO Certification in QMS

Pharmadex Screen shot in Nepal

NRA Assessors developing system requirement specifications to new MIS (Pharmadex)

SEARN: South-East Asia Regulatory Network

USAID MEDICINES, TECHNOLOGIES, AND PHARMACEUTICAL SERVICES (MTaPS) PROGRAM

Improved Access. Improved Services. Better Health Outcomes.

Building An Effective Medicines Registration System in Rwanda

John Patrick Mwesigye
Country Project Director
MTaPS Rwanda

USAID
FROM THE AMERICAN PEOPLE

What We Found in Rwanda

- Inadequate regulatory framework
- No institutional strategic plan
- Insufficient skill set for assessment of product dossiers
- Inadequate equipment and IT infrastructure for registration
- Inefficient registration process, unclear procedures
- Lack of QMS implementation
- Duplication of effort on performing evaluations of product dossiers registered by other reference authorities (WHO, US FDA)

What We Did in Rwanda

Development of Regulation and Guidelines for Medicines Registration

- Regulatory framework for Rwanda FDA medicines registration system
- Guidelines on Good Review Practices, variations, and renewal of medicines registration

Capacity Building for 55 Medicines Assessors

- A virtual capacity building workshop on medicines dossier evaluation using the Common Technical Document (CTD) guidelines and Good Review Practices

QMS Implementation

- Phased QMS implementation involving performance of a situational analysis, documentation, and creation of awareness

Expedited Registration of COVID-19 vaccines

- Supported establishment of WHO Collaborative Registration Process (CRP) mechanism

Why It Matters to Rwanda

- Strong, efficient registration system ensures access to safe and efficacious medicines and medical products
- Reduces substandard and falsified products in the market
- Builds confidence of population in the health system
- Improves patient outcomes
- Promotes local and international investment in the pharma sector

What's Next for Rwanda

- Conduct internal audit to determine readiness for ISO 9001:2015 certification
- Develop an eLearning course to facilitate continuous education about medicines evaluation, both as a refresher course and for new assessors
- Continue support to develop skill set for evaluations in specialized areas, such as bioequivalence studies and evaluation of biologics and vaccines

MTaPS: Lessons Learned

Kate Kikule
Principal Technical Advisor
Regulatory Systems Strengthening
MTaPS

USAID
FROM THE AMERICAN PEOPLE

Lessons Learned (1)

- The **WHO GBT process provides a great window of opportunity** to strengthen regulatory systems in low- and middle-income countries.
- **Updating laws and regulations in line with international standards**, including Good Reliance Practices, is critical to strengthening regulatory systems and improving access to quality-assured medicines.
- **Fostering regional and international collaboration** through reliance, recognition, and harmonization expedites the registration of medicines and improves regulatory efficiency.

Lessons Learned (2)

- **Establishing and implementing QMS** is an enabler to smooth and efficient medicines registration system.
- Establishing **efficient electronic management information systems** improves transparency and efficiency of the registration process.
- **Capacity building of assessors** assures quality of assessments.
- **Monitoring and evaluation** is key to mark progress and identify weaknesses for improvement.

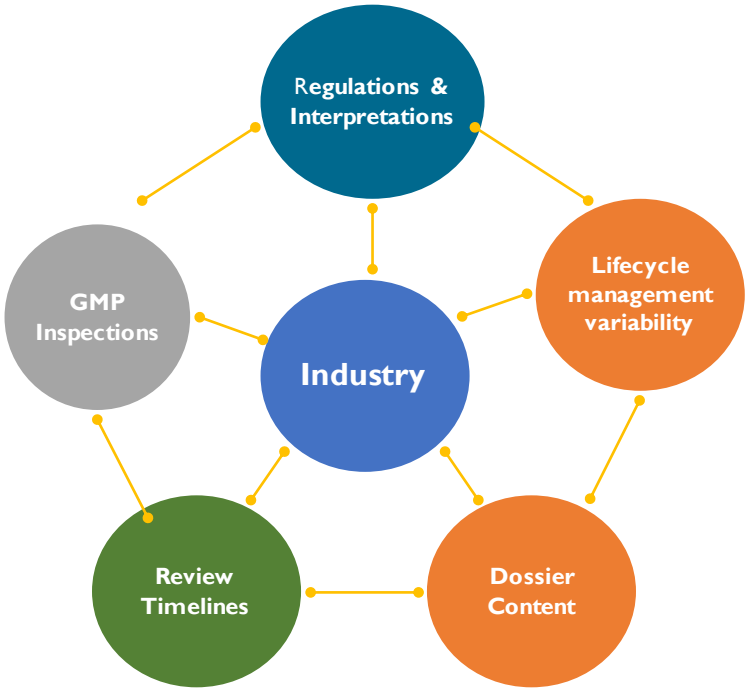
MTaPS Publications

- Guzman J., O'Connell E., Kikule K, Tamara H., The WHO Global Benchmarking Tool: Game Changer for Strengthening National Regulatory Capacity
- Twesigye G., Hafner, T., Guzman, J., Making the investment case for national regulatory authorities
- Technical Brief: Improving Access to MNCH Medical Products: Considerations for Effective Registration Systems

Catalyzing Pharma Industry and R&D in Africa through Stronger, Harmonized Medicines Registration Systems

Dr. John M. Mwangi
Head, Regulatory Affairs & Quality Assurance,
East & West Central Africa, **Bayer East Africa Ltd.**
Co-Chair Africa Regulatory Network (ARN)
International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)

Medicines Registration Systems in Africa



Industry Perspective

- Last decade has seen progressive growth in the pharmaceutical industry and accompanying regulatory environment in Africa.
- Key requirements and procedural challenges tend to hamper timely regulatory approvals, negatively impacting medicines access in many African countries.
- Countries remain in a continuum of maturity at national level; there has been significant efforts towards convergence.
- **Strong regulatory systems on the continent are key enablers for patient access to safe, effective, and high-quality medicines and vaccines.**

Industry appreciates the need to continue supporting a strengthening of regulatory systems in Africa, e.g., harmonizing the processes and requirements for medicines regulation and calls on support of other stakeholders.

Why Invest in Strengthening Medicines Regulatory Systems in Africa

Benefits
to Patients, Regulators & Industry

- **Predictable and fast access** to new, innovative health technologies & products
- **Reliable, sustainable supply chain,** e.g., handling of PACs*
- Common, global standards – **same standard for all**
- Production and **supply pooling** by manufacturers
- Integrated **scientific knowhow** among healthcare providers
- Assurance of **high quality, safe medicines** for all
- **Integrated market control** – reduced substandard products across country borders
- Attracts **local/regional manufacture** of medicines with assured quality/safety standards

*Post Approval Changes

How Can We Collaborate & Support Strengthening Medicines Regulatory Systems in Africa

Facilitating Factors

- Harmonization and convergence of regulatory requirements, which is central to **efficient utilization of limited resources**
- Encouraging and supporting countries to focus on value-adding activities to **minimize administrative hurdles**
- Capacity building towards evidence-based**, scientific regulatory decisions**
- Supporting alternative regulatory pathways and good regulatory practices, including **work sharing, reliance practices** for best resource utilization and overall cost reduction to the healthcare system
- Infrastructure support towards efficient regulatory agencies, e.g., **through robust IMS platforms**
- Supporting ongoing **Africa Medicines Regulatory Harmonization** towards establishment of Africa Medicines Agency

Q&A

Moderator
Javier Guzman
Technical Director
MTaPS

USAID
FROM THE AMERICAN PEOPLE

Closing Remarks

Javier Guzman
Technical Director
MTaPS

USAID
FROM THE AMERICAN PEOPLE

Contact

USAID MTaPS COR Lead
Alexis Leonard, aleonard@usaid.gov

Prime Contractor
Management Sciences for Health (MSH)

Learn more about MTaPS
www.mtapsprogram.org

Thank You

USAID
FROM THE AMERICAN PEOPLE