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

Improved Access. Improved Services. Better Health Outcomes.

Strengthening Pharmaceutical Regulatory Systems in the Asian Region

SESSION 1

Wednesday, July 12, 2023

2pm – 4.30pm

USAID
FROM THE AMERICAN PEOPLE

INTRODUCTION & OPENING REMARKS

USAID Welcome Remarks - Jean-Jacques Frere, Senior Health Governance Advisor, Asia Bureau/TS

Webinar objectives

Main objective

- To convene key regulatory regional networks and national regulatory authorities to discuss progress in advancing medicine regulatory systems in Asia

Sub-objectives

- To understand what regulatory authorities and regional networks (NRAs, SEARN, etc.) are doing regarding regulatory systems strengthening in the Asian region
- To discuss existing needs, and gaps in regulatory system strengthening
- To discuss strategies and interventions to address identified gaps
- To share approaches and methods used by USAID MTaPS program to improve specific regulatory system functions

Housekeeping

Please remember to sign in using the link to the attendance sheet in the chat.

				
Ensure that your audio and video connection are in working order	Mute your microphone during the presentation Turn off your camera while the presentation is ongoing	Reserve questions for the Q&A; or you may write your questions in the chat box Should you wish to make a comment or feedback, kindly make a note in the Chat Box and you will be recognized	Indicate that you are done sharing or speaking by saying, '**Over**' Avoid interrupting other people when they're speaking (or attempt to speak over them)	This event is being recorded.

Agenda Session 1

2.00 – 2.10 pm	**Welcome** Introduction and Opening Remarks: *MTaPS, PQM+, and WHO* Housekeeping: *Shahreen Haq, MTaPS* Overview of the Program: *Andrew Brown, MTaPS*
2.10 – 2.25 pm	**What is the Status of Pharmaceutical Regulation Globally?** *Alireza Khadem, WHO*
2.25 – 2.40 pm	**Regulatory Systems Gaps in Asia:** *Azad Kalam, MTaPS*
2.40 – 2.55 pm	**Pharmaceutical Registration System in Nepal:** *Shiwani Khadgi, DDA Nepal*
2.55 – 3.05 pm	**Facilitated Questions:** *Andrew Brown, MTaPS*
3.05 – 3.10 pm	**Ice Breaker and Stretch**
3.10 – 3.25 pm	**Regional Capacity Building Strategies for Pharmaceutical Regulatory Systems:** *Adrien Inoubli, SEARO*
3.25 – 3.40 pm	**Evidence-Based Approach to Developing the Regulatory Workforce:** *Vivian Rakuomi, MTaPS*
3.40 – 3.55 pm	**Minimum Common Standards for Regulatory Information Management Systems:** *Kate Kikule, MTaPS & Souly Phanouvong, PQM+*
3.55 – 4.10 pm	**Regulatory Information Management Systems:** *Deane Putzier, MTaPS*
4.10 – 4.20 pm	**Q&A**
4.20 – 4.30 pm	**Closing:** *Vivian Rakuomi, MTaPS*

WHO Regulatory Systems Strengthening

Global Status of National Regulatory Authorities

Presented by: Alireza Khadem
WHO/RPQ/REG/RSS

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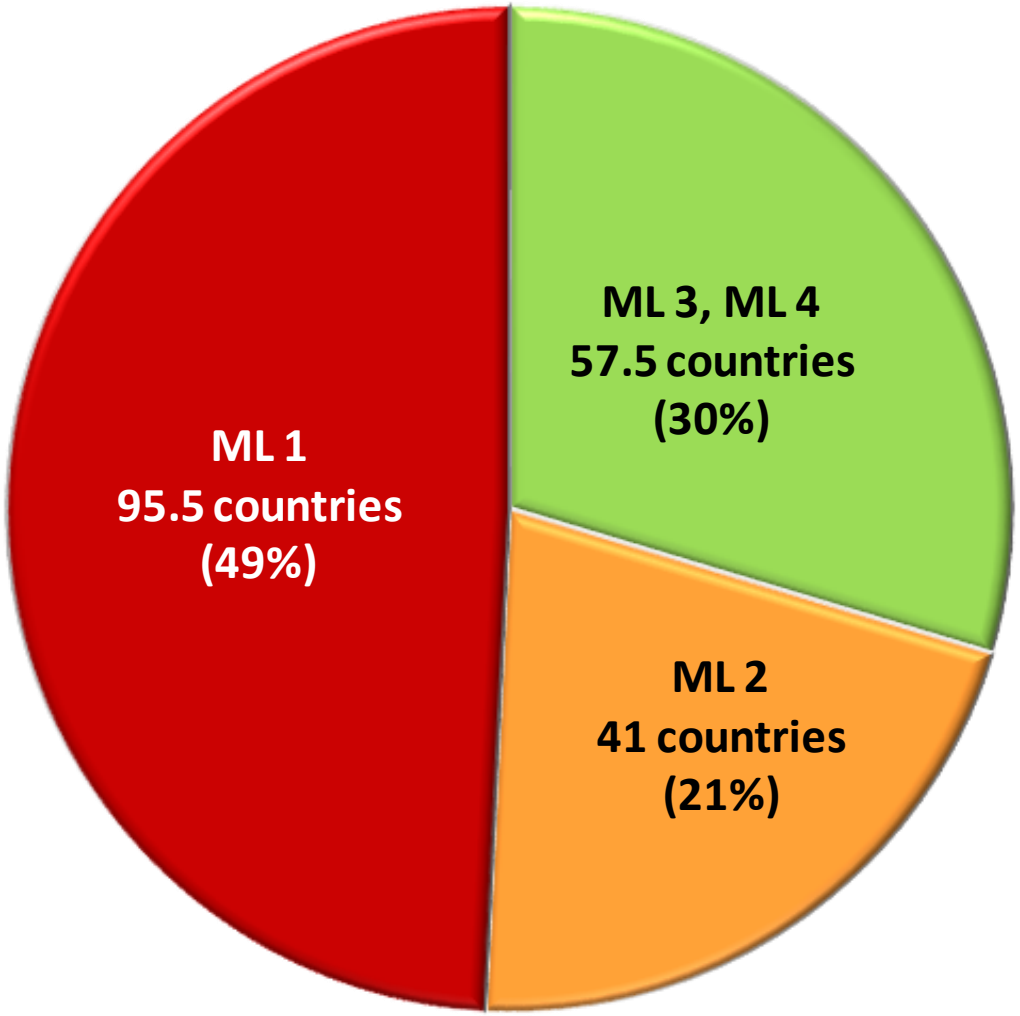
Overall regulatory systems' maturity level of WHO Member States and major challenges



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June 2023

WHO Regulatory Strengthening Activities

- **Resolution WHA 67.20 in 2014**
  - ✓ Recognized the importance of strong regulatory systems to a well-functioning healthcare system and the attainment of health-related SDGs and UHC

WHO supports Member States in reaching and sustaining effective regulatory oversight of medical products through the regulatory systems strengthening (RSS) programme

Objectives of the RSS programme

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

Ultimate goal

- ***Promote access to quality assured medical products***

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WHO Regulatory Action Plan: 2019-2023

Four strategic priorities

1. Strengthen country and regional regulatory systems
2. Improve regulatory preparedness for public health emergencies
3. Reinforce and expand WHO prequalification & product risk assessment
4. Increase the impact of WHO regulatory support activities

- Guiding WHO regulatory strengthening activities
  - ✓ Benchmarking and technical assistance to address regulatory gaps
  - ✓ Promoting regulatory convergence, harmonization, work-sharing and reliance mechanisms
  - ✓ Improving countries' ability to carry out risk-based post-marketing surveillance to securing supply chains against substandard and falsified products & safety monitoring of authorized products (vigilance)
    - Includes strengthening national quality laboratories
  - ✓ Promote and support sustainable and quality-assured local production through technical assistance

https://www.who.int/medicines/news/2019/strong-reg-systems-to-reach-UHC/en/

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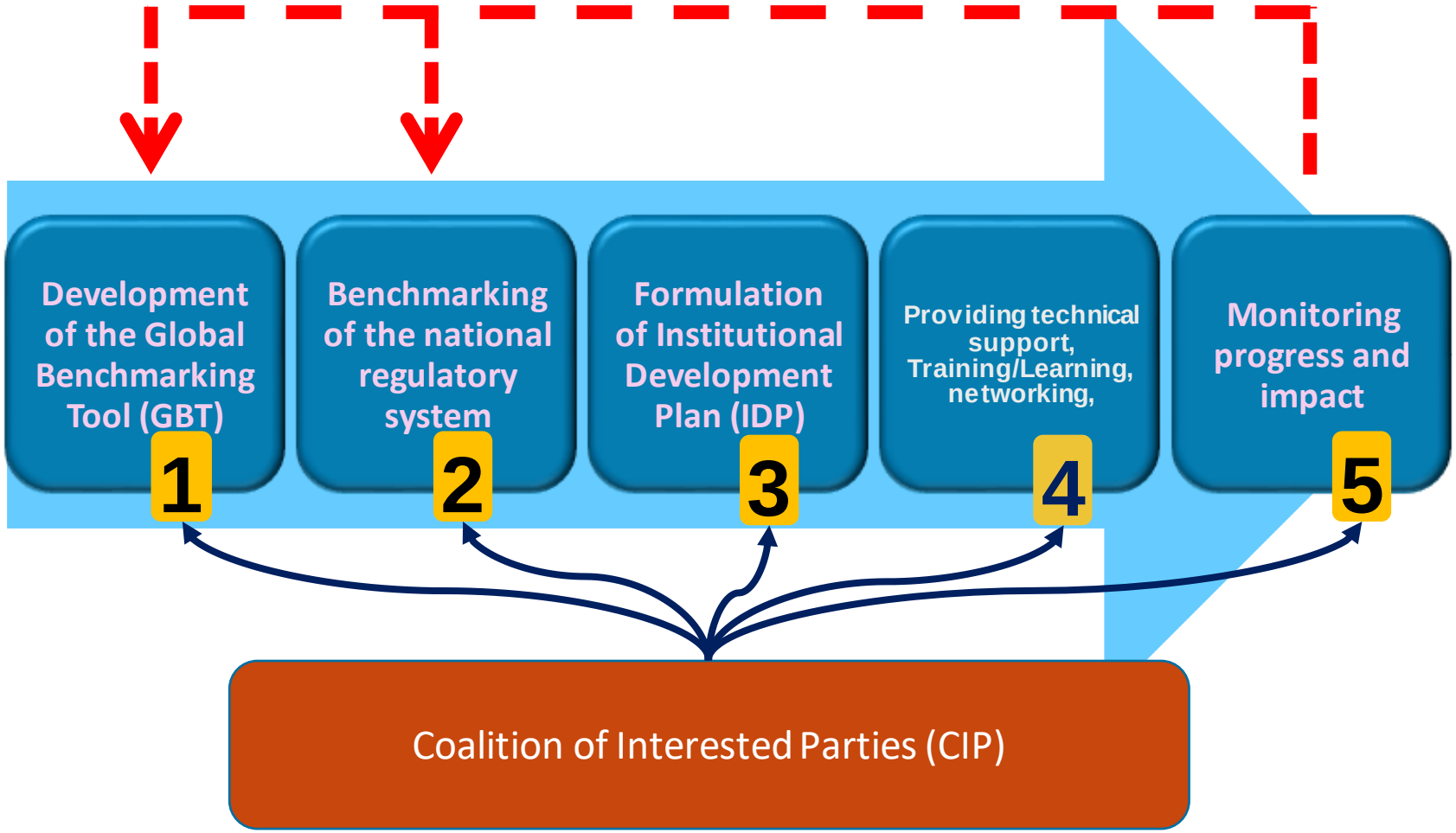
WHO Five-Step Capacity Building Model for National Regulatory Authorities (NRAs)

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



- Stable, well functioning and integrated regulatory system
- Eligibility for vaccine PQ
- WHO listed authorities (WLA)

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WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems of medical products: Revision VI

Link: https://apps.who.int/iris/handle/10665/341243

Blood (Nov 2019)

Medical Devices (Q2 2022)

Link: https://www.who.int/tools/global-benchmarking-tools

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WHO Regulatory System Strengthening Programme
Global status of benchmarking of regulatory systems (2016 – Jun 2023)

Self Benchmarking

1. Algeria
2. Afghanistan
3. Albania
4. Angola
5. Benin
6. Bhutan
7. Bolivia
8. Bosnia and Herzegovina
9. Botswana
10. Burkina Faso
11. Cameroon
12. Cape Verde
13. Central African Republic
14. Chad
15. Comoros
16. Democratic Republic of the Congo
17. Costa Rica
18. Cote d'Ivoire
19. Djibouti
20. Ecuador
21. Equatorial Guinea
22. Eswatini
23. Gabon
24. Gambia
25. Guatemala
26. Guinea
27. Guinea-Bissau
28. Honduras
29. Iraq
30. Islamic Republic of Iran
31. Jordan
32. Kyrgyzstan
33. Lebanon
34. Liberia
35. Madagascar
36. Malaysia
37. Maldives
38. Mali
39. Mauritania
40. Mauritius
41. Mongolia
42. Montenegro
43. Namibia
44. Nepal
45. Nicaragua
46. Niger
47. North Macedonia
48. Panama
49. Peru
50. Philippines
51. Republic of Congo
52. Senegal
53. Seychelles
54. Sierra Leone
55. Syrian Arab Republic
56. Togo
57. Tunisia
58. Ukraine
59. Zambia

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95 = 74%

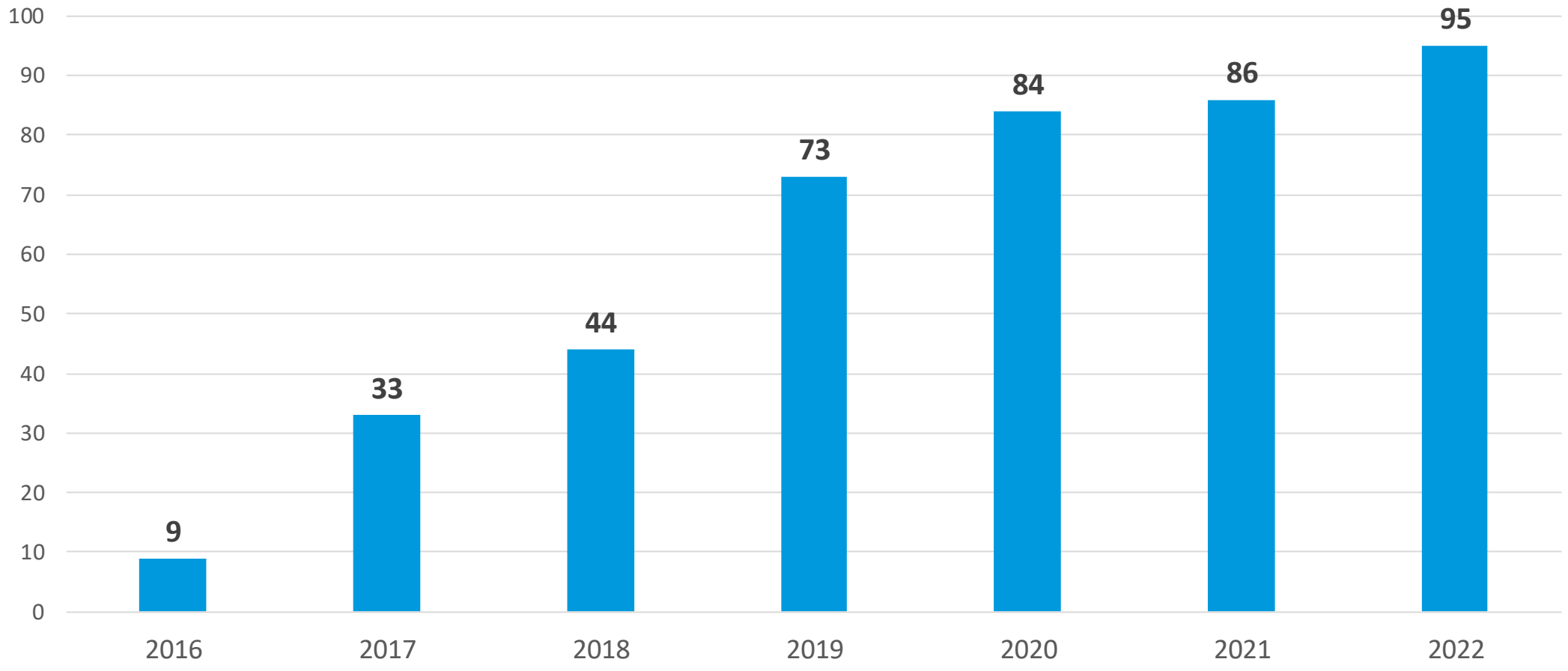
Member-states World population

Benchmarking

1. Bangladesh
2. Burundi
3. Cambodia
4. People's Republic of China
5. El Salvador
6. Egypt
7. Eritrea
8. Ethiopia
9. Ghana
10. India
11. Indonesia
12. Kazakhstan
13. Kenya
14. Lao People's Dem Rep
15. Malawi
16. Mozambique
17. Nigeria
18. Pakistan
19. Papua new guinea
20. Rwanda
21. Saudi Arabia
22. Serbia
23. Singapore
24. Somalia
25. South Africa
26. South Korea
27. South Sudan
28. Sri Lanka
29. Sudan
30. Türkiye
31. United Republic of Tanzania
32. Thailand
33. Timor-Leste
34. Uganda
35. Viet Nam
36. Zimbabwe

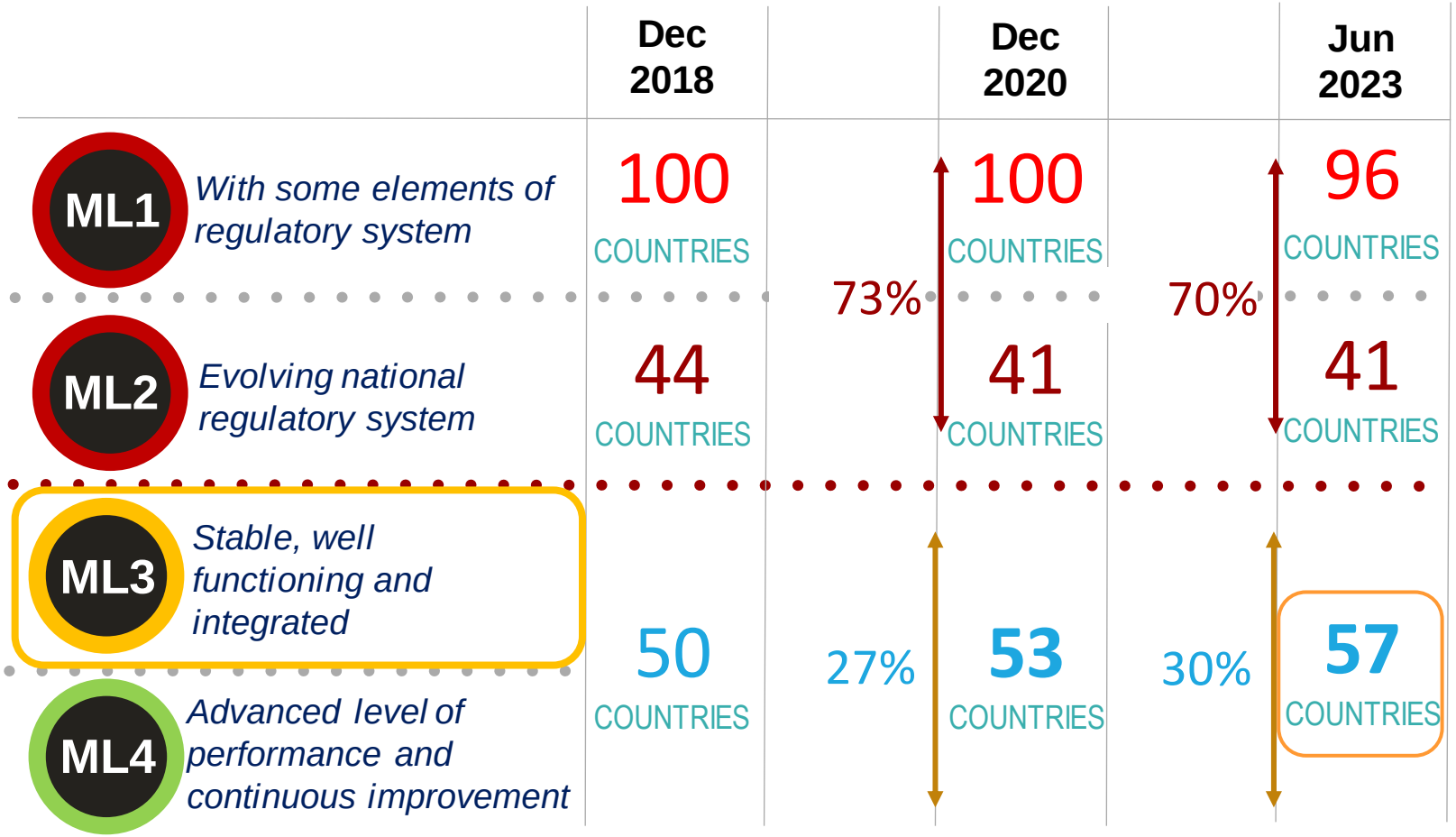
Number of Member States benchmarked by GBT by year

- Cumulative bar chart



Current levels of maturity of national regulatory systems

WHO GBT (for medicines and vaccines: as of June 2023)



- Vaccines produced in countries with ML 3/ML 4 are eligible for EUL or prequalification,
- 34 of 57 (65%) countries are meeting ML 3 requirements as vaccine-producing countries

ML3 **GOAL of WHA Resolution 67.20**

ML: *(regulatory system) maturity level*

- **Singapore** medicines regulatory system, the world's first to achieve maturity level (ML4) *(Feb 2022)*
- **Egypt** vaccine regulatory systems reach ML3 *(Mar 2022)*
- **Nigeria** medicine regulatory systems reach ML3 (*Mar 2022)*
- **China** vaccine regulatory system reaches ML3 *(Jul 2022)*
- **South Africa** vaccine regulatory system reaches ML3 *(Oct 2022)*
- **Republic of Korea** achieves the highest WHO level for regulation of medicines and vaccines *(Nov 2022)*

Major challenges

- Human resources: quantity and competency
- Sustainability of the regulatory activities linked to donors' support: e.g. HR capacity, Post-market surveillance plans
- Pharmacovigilance function: under-reporting
- Additional regulatory activities/functions to be implemented for countries to expand to local production or production of vaccines
- Producing countries
  - GMP compliance of the local manufacturer and enforcement by NRA
  - Bioequivalence studies

Objectives of WLA initiative

01 To provide a transparent and evidence-based pathway for RAs to be globally recognized

02 To promote access and the supply of safe, effective and quality medical products

03 To optimize use of limited resources by **facilitating reliance**

Policy document:

The Policy describes the purpose, definitions and high-level operating principles related to the evaluation and public listing of authorities

Link: https://www.who.int/publications/i/item/9789240023444

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Coalition of Interested Parties (CIP) Network

launched in 2021, now with 21 members

A voluntary Network established by the WHO

Interested entities need to apply to become a member of the CIP Network

Dec 2020: Publication of CIP ToR

Sept 2021: Launch of CIP

March 2022: First Kick-Off Meeting for CIP Members

April 2022: Launch of CIP Implementation in-country

October 2022: First CIP Global Steering Group Meeting

December 2022: First CIP Regional Steering Group Meeting (Africa)

February 2023: CIP In-Country Meeting – Coordinating partner support in Senegal

March 2023: CIP GSG Work Plan Development meeting & development of Strategic Plan

March 2023: CIP RSG AMRH PP – First meetings of the Technical Partners Group and Funders Group

Purpose:

To establish and promote a unified strategic and coordinated approach to strengthening national and regional regulatory systems

Aim:

To increase the effectiveness of collective efforts and desired impact in countries and regions.

- The CIP Network's activities span the lifecycle of regulatory system strengthening efforts
- The WHO five-step capacity building model will guide the roles and activities of the CIP members
- The nature and scope of collaboration between the NRA & the CIP member(s) will be set forth in an agreed Terms of Reference & Support Plan
- The CIP web platform will serve as a secure, central repository for information sharing

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Contact the CIP Secretariat: **cip_network@who.int**

Global Competency Framework

AIM: Systematic approach to support training & professional development of regulatory staff

- Practice Activities
- Competencies
- Levelling

Role-specific related competencies

Beneficiaries

Methods for human performance assessment

Types of appraisals

- Self-appraisal (assessing yourself)
- Appraising another person within the organization (peer or supervisor appraisal)
- External validation (appraising another person from another organization)

Key outputs

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WHO Good Regulatory Practices and Good Reliance Practices Launch Webinar

Annex 10

Good reliance practices in the regulation of medical products: high level principles and considerations

Background

WHO supports reliance on the work of other regulators as a general principle in order to make the best use of available resources and expertise. This principle allows leveraging the output of others whenever possible while placing a greater focus at national level on value-added regulatory activities that cannot be undertaken by other authorities, such as, but not limited to: vigilance, market surveillance, and oversight of local manufacturing and distribution. Reliance

Annex 11

Good regulatory practices in the regulation of medical products

Background

A fundamental role of government is to protect and promote the health and safety of the public, including by delivering health care. A well-functioning health care system requires available, affordable medical products that are safe, effective and of assured quality. As medical products are essential in the prevention, diagnosis and treatment of disease, the consequences of substandard and falsified medical products can be life threatening. This is a concern, as users of medical products

WHO Expert Committee on Specifications for Pharmaceutical Preparations: Fifty-fifth report. Technical Report Series; 2021.

Link: https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations

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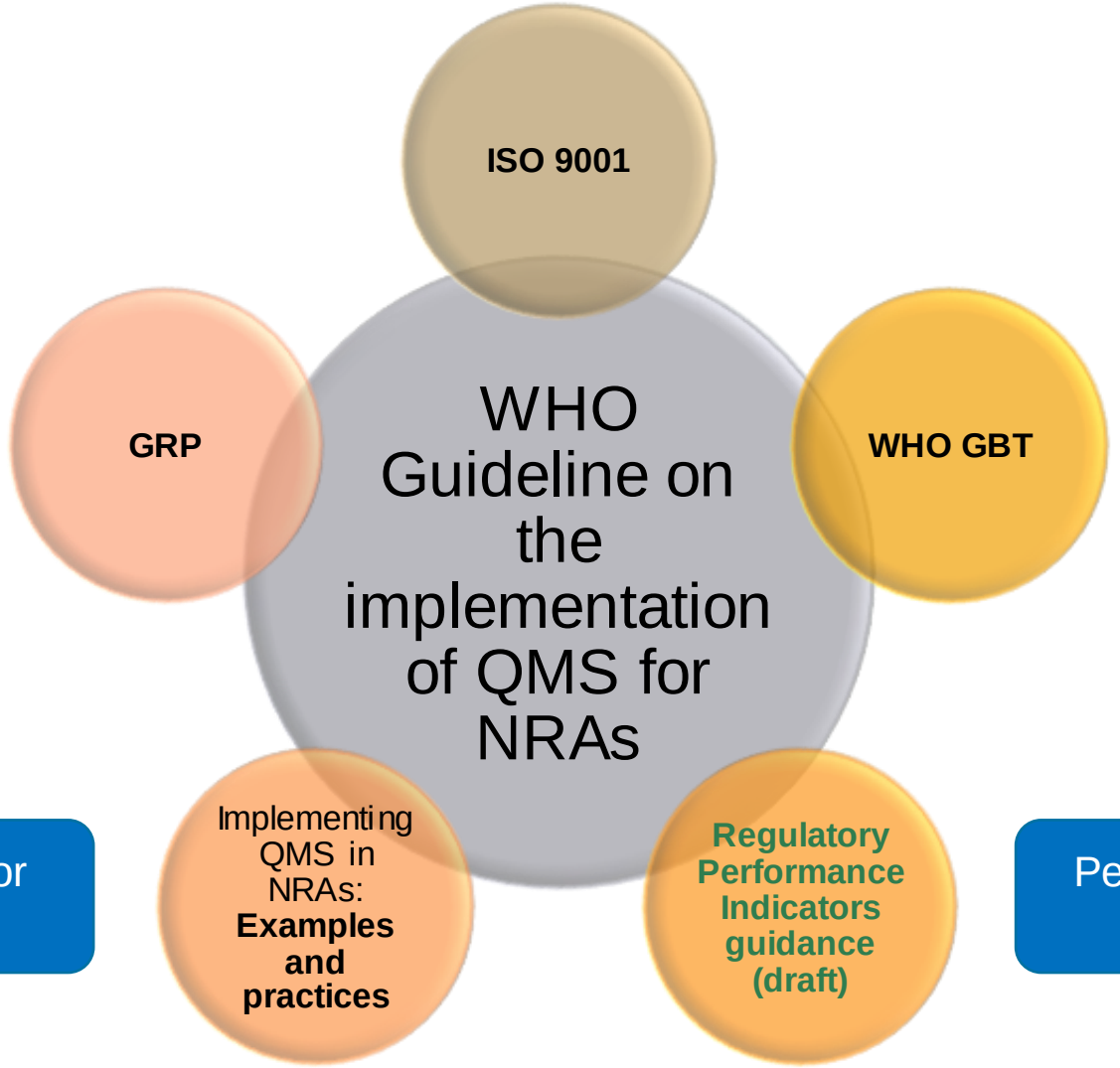
Concept, principles and requirements

A robust and well-functioning quality management system one of the enablers of GRP

Regulatory Systems Strengthening



Additional guidance for implementation

Performance evaluation and improvement

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Thank you
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MTaPS SUPPORT TO STRENGTHENING REGULATORY SYSTEMS IN ASIA

Azad Abul Kalam
Senior Technical Advisor, Regulatory Systems Strengthening
USAID MTaPS Program

Outline

- Overview of Regulatory System Strengthening
  - MTaPS Regulatory System Strengthening Approach
- Regulatory Systems in Asia: What we found
- MTaPS Focus Activities for Regulatory System Strengthening
- Next Priorities for Asian Region
- Resources

Overview of Regulatory System Strengthening

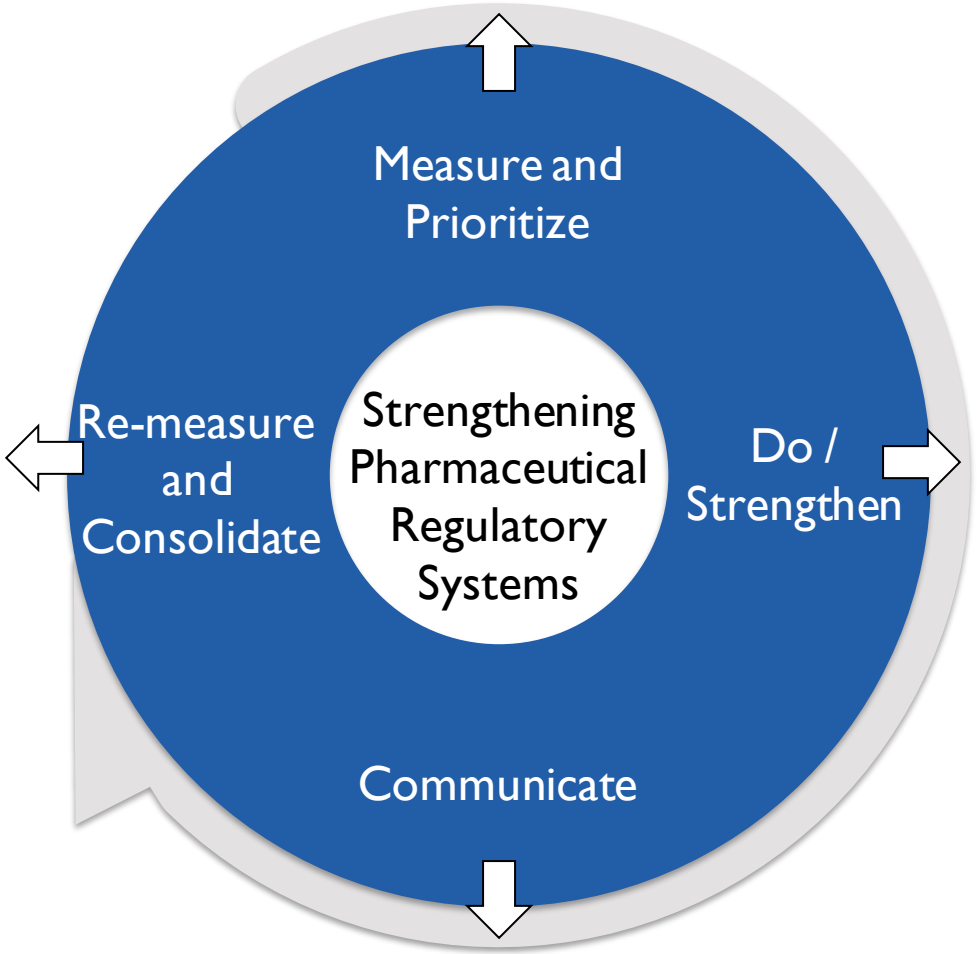
- National Regulatory Authorities (NRAs) play a key role in assuring the quality, safety, and efficacy (QSE) of medical products.

- Effective regulation of medicines promotes and protects the publics' health by guaranteeing medicines' QSE and ensuring access to and availability of quality products.

- MTaPS provides technical assistance to strengthen regulatory systems in countries throughout Africa, Eastern Europe, and Asia to:
  - Build regulatory capacity within NRAs.
  - Promote regulatory cooperation, convergence and harmonization.

USAID MTaPS Regulatory System Strengthening (RSS) Approach

WHO Global Benchmarking tool and rapid assessments produce institutional development plans (IDPs)



Increase functional level (Aim for Level 3)

Implement IDPs with key strategies in mind:

- Risk-based regulation
- Harmonization
- Reliance

Regulatory Systems in Asia: What we found

Using the WHO GBT and MTaPS mapping exercises, we found:

- Most country's regulatory systems are still below WHO Maturity Level 3.
- Weak governance and lack of transparency, accountability, and integrity.
- Some of the NRAs regulatory processes are not harmonized with global standards.
- Significant gaps in the regulatory framework including legal and regulatory provisions.
- Quality Management System (QMS) not fully established in some NRAs.
- Weak collaborations with other regulatory authorities / systems / networks.
- Inadequate resources (HR, financial, infrastructure, equipment, ICT systems).

We also mapped stakeholders actively engaged in RSS in Asia, and these included 18 regional networks, of which we decided to collaborate with ASEAN, SEARN, and WHO to strengthen the regulatory systems in the region.

MTaPS Focus Activities for Regulatory System Strengthening in Asia

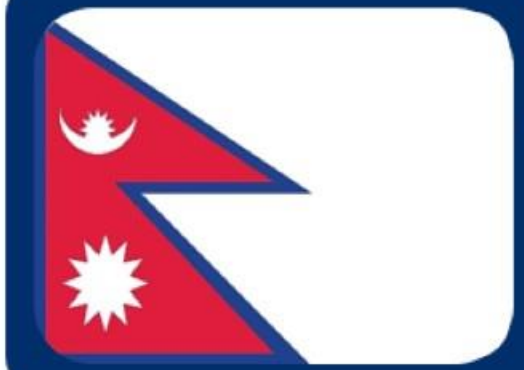
1. Strengthening Regulatory Legal Frameworks and Policies

- The legal framework is critical to ensure a robust regulatory system and should be aligned to National policies and international regulatory best practices

- MTaPS is assisting countries to adopt model policies, legislations, regulations, guidelines, and norms to regulate medical products: Nepal, Philippines, Bangladesh

- The regulatory frameworks developed take into consideration:
  - A concise regulatory structure aligned to model international laws/regulations
  - Adequately articulate regulatory and legislative objectives and scope
  - Principles of best practice and indicators for performance evaluation
  - Assessment of impact and feasibility of application
  - Stakeholder engagement

Example: Strengthening Regulatory Legal Frameworks and Policies



Nepal

- Facilitated revisions and update of the legal & regulatory framework by revision of the national drug policy as well as the medicine law and developed regulations for various regulatory functions e.g. medicine registration, pharmacovigilance, inspection & registration of premises.

Philippines

- Supported FDA in updating the national PV policy and developed the PV guideline to ensure that PV is supported by a comprehensive set of policy provisions with the necessary mandate for implementation.

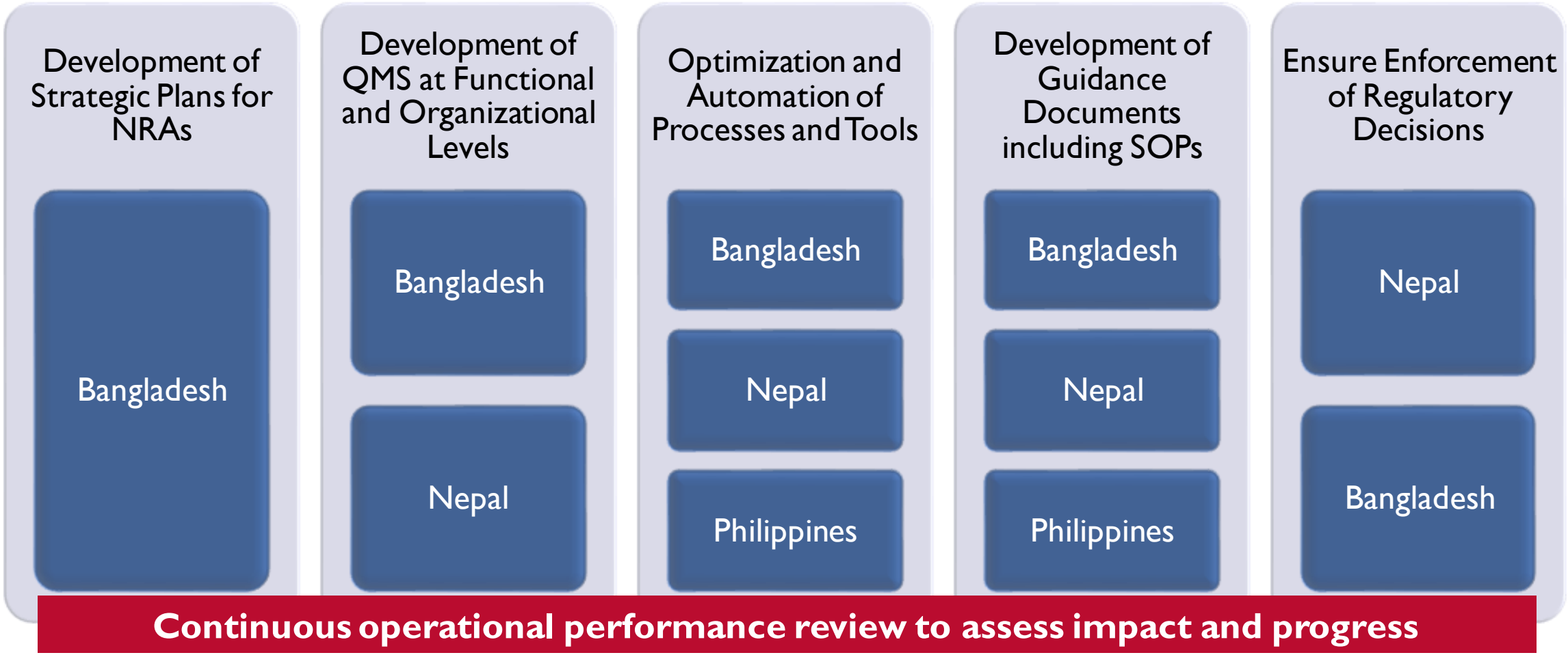
2. Strengthening Regulatory Organization and Structure

- The governance system and organizational structure are requisite mechanisms that inform the success of the regulatory system.
- MTaPS is working with NRAs to establish mechanisms to ensure decision-making, oversight, and enforcement of policies, laws, and regulations based on the following components of good regulatory practices:
  - Independence
  - Impartiality
  - Transparency
  - Clarity

Example: Restructuring Nepal Directorate of Drug Administration (DDA)

- Advocated with the Government of Nepal (GON) to update current drug law and include a new proposed structure and staffing norms for the DDA to help it perform its key regulatory functions more efficiently.
- Drafted concept note for the Nepal MOHP on the legislative revision and the required re-organization and decentralization of the DDA.
- Helped GON reorganize the DDA, undertook a comparative survey of 10 NRAs in 2020.
- Collaborated with DDA to hold a re-organization conference, draft a revised structure, and prepared updated staffing norms.

3. Strengthening Regulatory System Functions and Processes



4. Optimizing the Pharmaceutical Systems Workforce

4 Pathways Needed to Optimize Workforce Performance

Staffing	Skills	Working Conditions	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
• Ability to recruit quality candidates • Adequate pool of workers • Sufficient budget	• Adequate technical & managerial competencies • Staff have leadership skills • Understand roles & responsibilities	• Favorable social & emotional environment • Physical environment is safe, clean, and conductive to performance • Up-to-date, relevant tools & equipment	• Good performance supported • Workers have a sense of ownership of their role • SC workers understand and care about their role in the HC system

Example: Strengthening Regulatory Capacity of NRAs

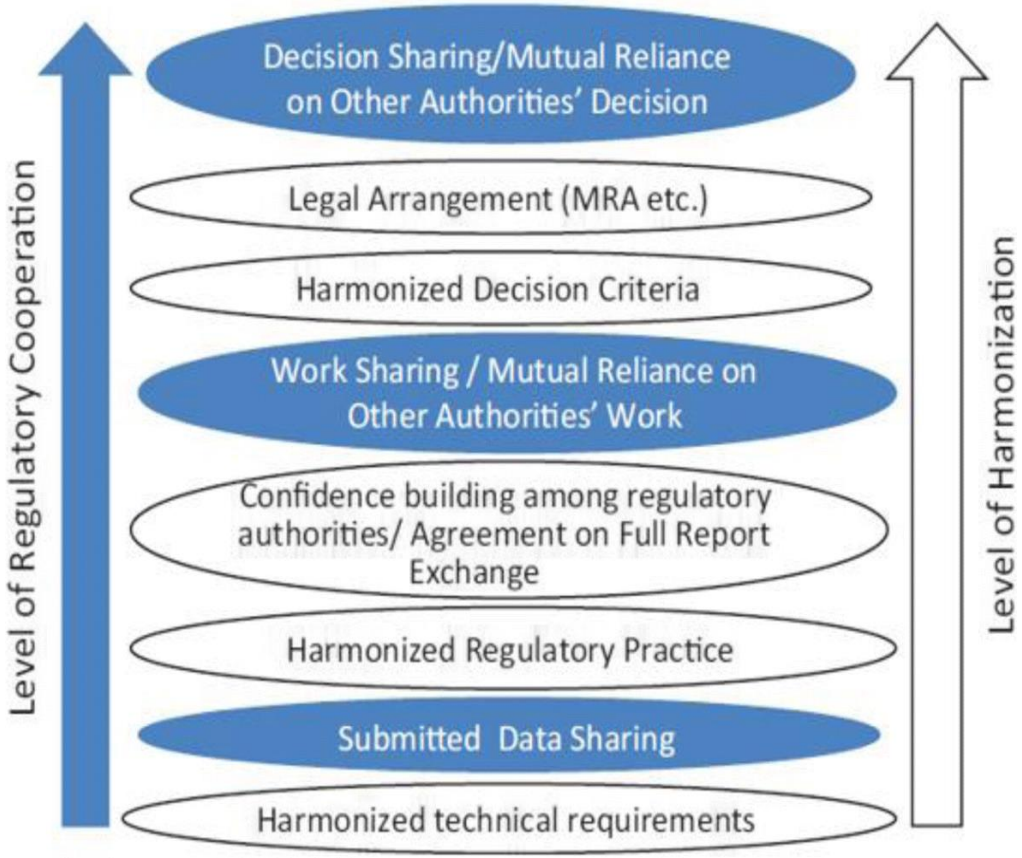
Assisted in building the technical capacities and competencies of NRA staff	Bangladesh Nepal Philippines
Qualified and adequate experts are required to perform critical regulatory functions	Established organization structure and develop job descriptions Bangladesh, Nepal Capacity development of regulatory personnel -Bangladesh, Nepal, Philippines
Competency mapping using the WHO competency framework for regulators is one way of building skills, knowledge and experience to undertake regulatory work	Bangladesh Nepal Philippines

5. Strengthening Collaborations and Harmonization of Medical Products Regulation

Support coordination and advocacy efforts for regional harmonization through regional networks and platforms (e.g., Association of Southeast Asia Nations, South-East Asia Regulatory Network)

Joint learning and exchange of information between regional member states (ASEAN, SEARN)

Twinning/benchmarking programs with other NRAs including SRAs (Nepal DDA with Indonesia BadanPOM)



Tominaga T (2013) The ICH, the GHTF, and the future of harmonization initiatives. Therapeutics Innov Regul Sci 47:572

Next Priorities for Asian Region

Legal framework

- Update/develop legal frameworks, policies, regulations

System automation

- Information management system and database for record management

Resource mobilization

- Financial support, human resources capacity strengthening and recruitment

Improved QMS

- Continuous improvement and improved M&E system

Collaborations and harmonization

- Participation in regional/global regulatory networks

Source: *USP PQM+ presentation*

Resources

WHO Expert Committee on Specifications for Pharmaceutical Preparations; fifty-fifth report, Annex-11: Good regulatory practices in the regulation of medical products

WHO Global Benchmarking Tool (WHO GBT)

WHO Global Model Regulatory Framework for medical devices including in vitro diagnostics for medical devices

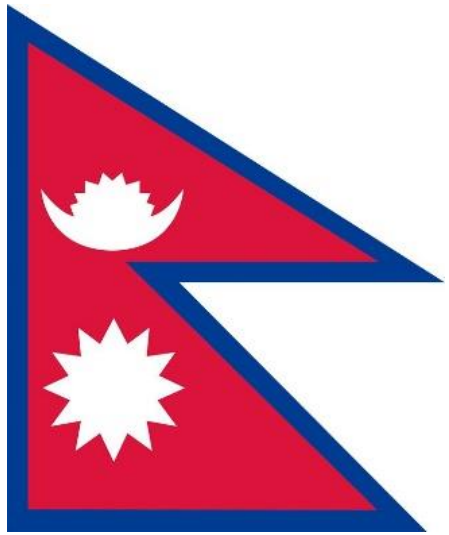
Regulatory System Strengthening; WHO

United Nations Sustainable Development Goals

WHO Global Benchmarking Tool

Khadem Broojerdi, A., et al., The World Health Organization Global Benchmarking Tool an Instrument to Strengthen Medical Products Regulation and Promote Universal Health Coverage. Frontiers in Medicine, 2020. 7

USP PQM+ Presentation on WHO GBT and RSS

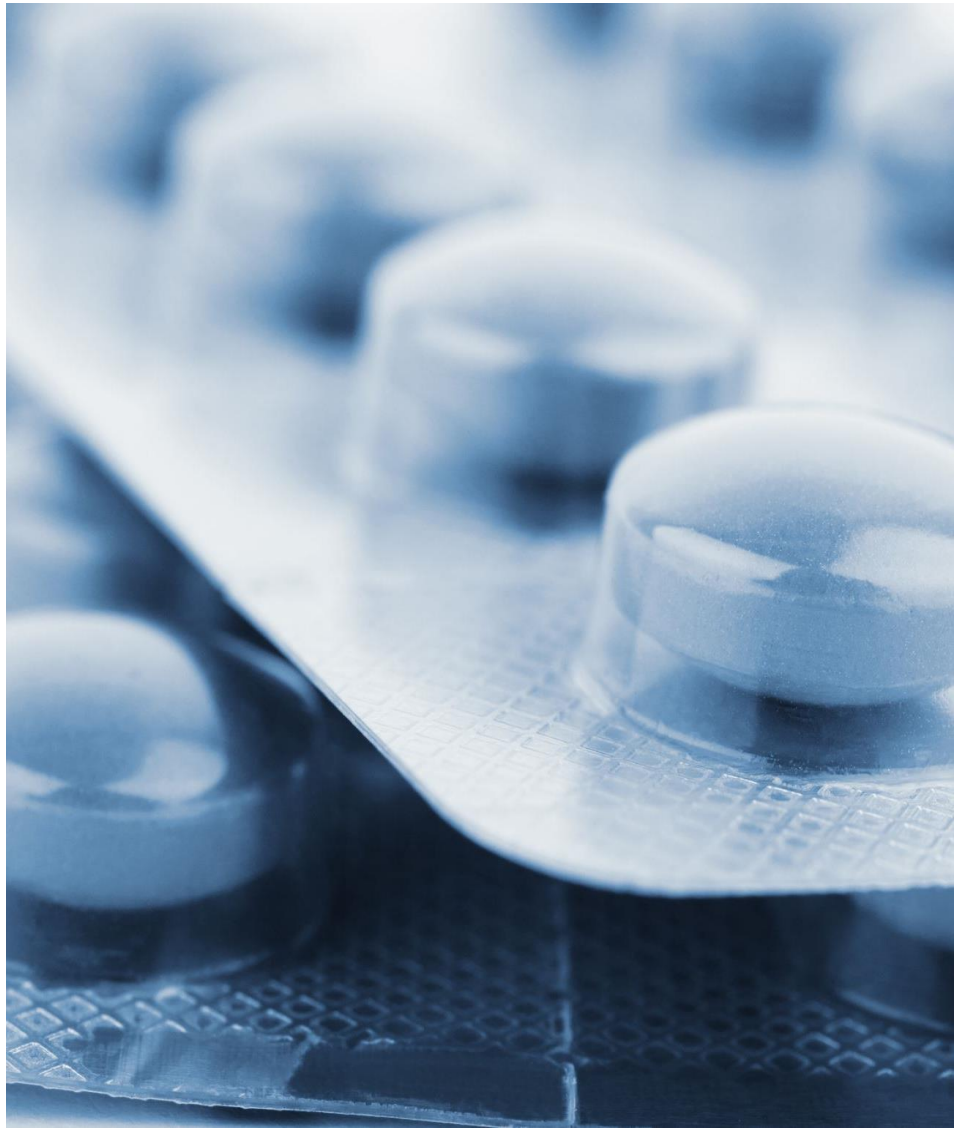


Pharmaceutical Registration System in Nepal: Current experiences and future priorities

The Government of Nepal
Ministry of Health and Population
Department of Drug Administration (DDA)
Nepal
July 12, 2023

Content of Presentation

- History and existing provision
- Functions of DDA
- Organogram
- DDA: Vision, Mission, Quality Policy
- Background: Pharmaceutical sector at a glance
- Registration system
- Support partners and their activities
- Current development and prospects
- Registration challenges
- Next steps and priorities for DDA
- Resources



History and Existing Provision

Legal frameworks

- National Medicines Policy 1995
- Drug Act, 1978
- Drug Consultative Council and Drug Advisory Committee Regulation 1980
- Drug Registration Regulation 1981 (amend. 2013, 2020, 2021)
- Drug Investigation and Inspection Rules 1983 (amend. 1991)
- Drug Standard Regulation 1986
- Codes on Sales and Distribution 2014
- National GMP Code 2015 (Amend. 2022)
- Import Provision 2015
- Special Permission Guidance 2017 (amend. 2021)

Central DDA and 3 DDA branch offices

National Medicines Laboratory

Staffing

DDA (National Regulatory Authority)
Central Office (Kathmandu): 49 staff
Nepalgunj Branch: 8 staff
Birgunj Branch: 9 staff
Biratnagar Branch: 9 staff

National Medicines Laboratory (National Control Laboratory)
Kathmandu: 40 staff

Total Staffs: 115 (DDA, NML, Branch Offices)

Establishment of DDA as National Regulatory Authority of Nepal in 1978 with following objectives:

- Prohibit misuse and abuse of drugs
- Prohibit false and misleading information
- Control on the drugs which are not safe for use by people, not efficacious and not of standard quality

Registration functions

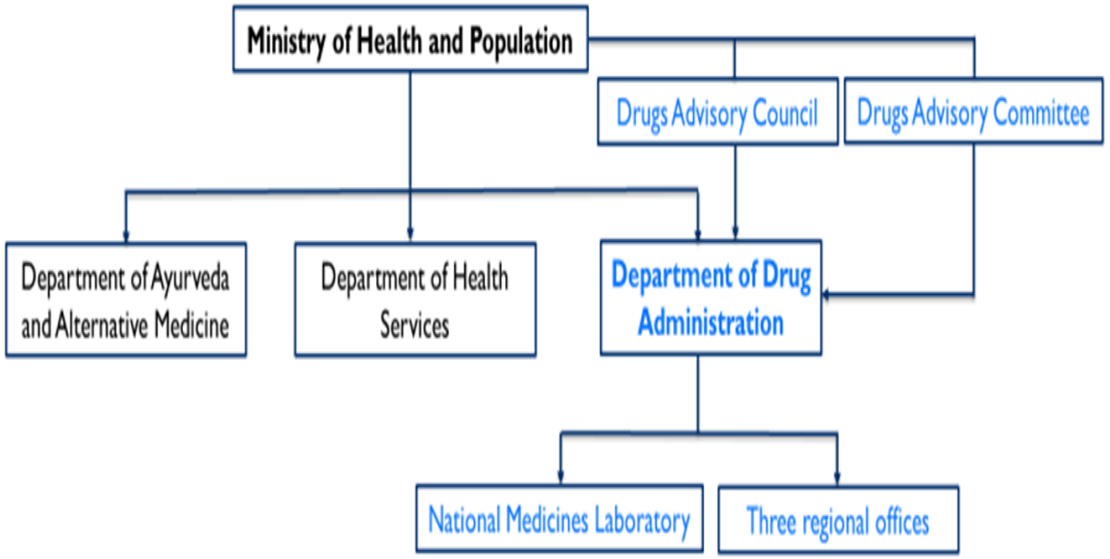
- Licensing/registration of
- Pharmaceutical industries and pharmacy
- Market authorization
- Post-marketing surveillance
- Clinical trial
- Inspection, investigation, prosecution and filing of cases
- Renewals

Service functions

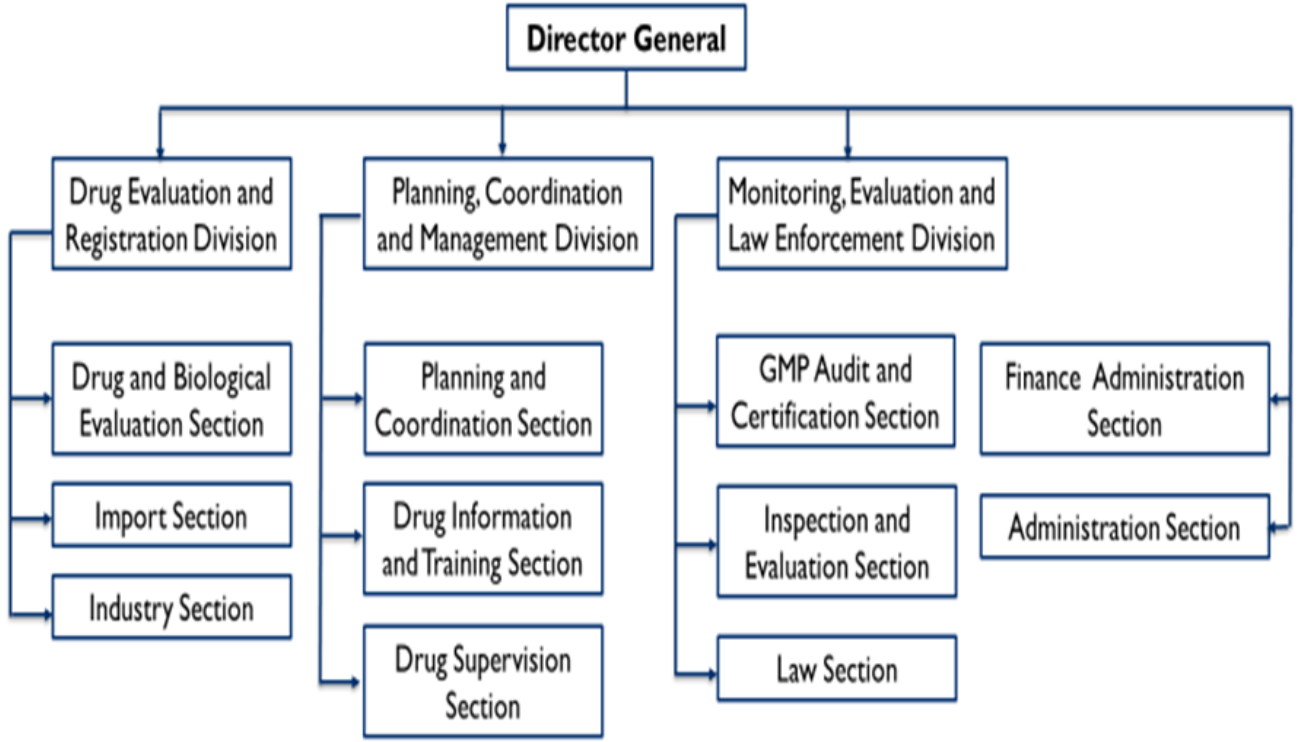
- Preparation of EML list
- Training and refresher for pharmacies
- Drug information and availability
- AMR containment and Return Unwanted Medicine (RUM)
- Promotion of domestic manufacturers
- Preparation of Nepal National Formulary

Organogram

Ministry and DDA



DDA Organogram



Vision, Mission and Quality Policy

Vision

- To protect and promote public health, ensuring access to safe, effective and quality–assured medicines and allied products.

Mission

- To provide regulatory oversight and evidence-based decisions for medicines and allied products, ensuring availability of safe, effective and quality medicine at affordable prices through the proper implementation of internationally adopted good practice as well as reliance and recognition.

Quality Policy

- DDA is committed to protecting and promoting the health of Nepalese people through good governance and evidence-based decision, ensuring access to safe, efficacious and quality-assured medicines and allied pharmaceutical substances in accordance with the Drug Act, Regulations and Guidelines.

Background: Pharmaceutical sector at a glance

$500 million (Approx.) Excluding HTP

128 domestic industries

52.27% total demand met by domestic manufacturers
$100 million essential medicines

Registered Pharmacy: 27,903
Importers: 169

16,990 brands

350 registered foreign companies

Same Legal Framework, Structure and Human Resources with expanding roles

Registration system

- Registration of pharmaceutical industries.
- Registration of medicines based on WHO Good Medical Practice (GMP) Guidelines and National GMP Code with regular inspections.
- Provision of Drug Consultative Council, Drug Advisory Committee, Drug Evaluation Committee, Analytical Method Validation Committee etc. for new drug registration and guidelines.
- Provision of availability of medicines based on public interest.
- Risk-based post-marketing surveillance of marketed product.
- Annual renew of license.

Nepal (DDA) is now officially listed as a participating member of Collaborative Registration Procedure (CRP) in 2022.

Active member of SEARN

PQ CRP: Collaborative Registration Procedure: 51 Participating NRAs, plus 1 Regional Economic Community

World Health Organization

As of 15 March 2022

Armenia
Azerbaijan
Bangladesh
Belarus
Botswana
Burkina Faso
Bhutan
Burundi
Cameroon
Cape Verde
*Caribbean Community (CARICOM)
Comoros
Cote d'Ivoire
Dem. Rep. Congo
Eritrea
Ethiopia
Gabon
Georgia
Ghana
Kazakhstan
Kenya
Kyrgyzstan
Lao PDR
Madagascar
Malaysia
Malawi
Maldives
Mali
Mauritania
Mozambique
Namibia
Nepal
Nigeria
Pakistan
Philippines
Republic of Congo
Rwanda
Senegal
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Uzbekistan
Yemen
Zambia
Zanzibar
Zimbabwe

* CARICOM
Member States: Antigua and Barbuda, Bahamas, Belize, Dominica, Grenada, Haiti, Jamaica, Montserrat, Saint Lucia, St. Kitts and Nevis, St Vincent and the Grenadines, Suriname and Trinidad and Tobago
Associate Member States: Anguilla, Bermuda, British Virgin Islands, Cayman Islands and Turks and Caicos Islands

Assessment of DDA using WHO Global Benchmarking Tool for NRA

- Self-benchmarking assessment conducted from February to March 2021. Follow up visit from WHO SEARO conducted in November 2022 to provide technical support for implementation of Institutional Development Plans (IDPs) - Maturity Level 1 (ML1).
- IDPs: 268.
- In response, Nepal has set target to enhance the regulatory capacity of the DDA, aiming to achieve ML 3 by 2027 as per the National Health Sector Strategy (2023-2030).
- Supporting partners: WHO, MTaPS and PQM+ programs to achieve the set target.
- Revision of law and regulation and implementation of Quality Management System (QMS) requisite for higher maturity.

EDP Partner Support

Ongoing activities	Partners
Regulatory system strengthening (ML 3 by 2025)	MTaPS, PQM+, WHO
National medicine policy revision	MTaPS, WHO
Drug Act revision	MTaPS
Quality manual and SOPs	MTaPS
GPP/GSDP guidelines	MTaPS
Risk-based post-marketing surveillance	PQM+, WHO
Software development	MTaPS
Antimicrobial consumption studies	FHI 360, WHO
Pharmacovigilance activities	MTaPS, WHO
Capacity building	MTaPS, PQM+, WHO

GPP: Good Pharmacy Practice
GSDP: Good Storage and Distribution Practice

Current Development and Prospects

Reorganization

Update of law & regulations

Revision of medicines policy

Full digitalization: (DDA-MIS)

Implementation of GPP and GSDP guidelines and indicator-based electronic inspection tools

Registration of health technology products, nutraceuticals and cosmeceuticals

Implementation of quality management system

Support Partners

- World Health Organization (WHO)
- Medicines, Technologies, and Pharmaceutical Services (MTaPS)
- Promoting Quality of Medicines Plus (PQM+)

Registration Challenges

- Law and regulations not up-to-date
- Limited staff to oversee high inspection numbers
- Province-wise offices not fully established
- Updated DDA-MIS: full digitalization
- No medical device regulation
- No medicine pricing regulation
- Lack of QA unit to oversee QMS implementation
- Thorough dossier evaluation
- Availability of diverse manpower in drug evaluation committees
- No pharmaceutical services unit at MOHP

Next Steps and Priorities for DDA

- Increase human resources.
- Revise framework, practices, procedures and structures.
- Attaining higher regulatory maturity.
- Implementation of all initiated, finalized and awaiting approval indicators.
- Improved ICT systems including DAMS and responsiveness.
- Foster harmonization, reliance and collaborations with international regulatory agencies.

Resources

- Drug Act 1978
- Medicine Registration Guidance
- Government of Nepal DDA
- Government of Nepal Medicine Registration portal
- Ministry of Health
- WHO Global Benchmarking Tool

Thank You!

FACILITATED Q&A

Andrew Brown
Principal Technical Advisor, Governance and Capacity Building
USAID MTaPS Program

ICE BREAKER & STRETCH

Regional Capacity Building Strategies for Pharmaceutical Regulatory Systems

MTaPS Virtual Webinar Series: Strengthening Pharmaceutical Regulatory Systems in the Asian Region

12-13 July 2023. Chennai, India

World Health Organization

Adrien Inoubli | Regional adviser for medical products regulation | Department of UHC/Health Systems (HSD) | SEARO | inoublia@who.int

Acknowledgment: HQ/RSS team, HQ/RCN team, SEARN

WHO South-East Asia Regional Office

- **A quarter of the world's population**
- **11 Member States**
  - Bangladesh, Bhutan, the Democratic People's Republic of Korea, India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, Thailand and Timor-Leste
- **Regional organization**:
  - Regional committee: representatives of the 11 Members States
  - Regional office led by an elected Regional Director
    - Dr Poonam Khetrapal Singh

World Health Organization

WHO South-East Asia Region

- Producing countries / importing countries
- Small – largest populations
- Archipelago – landlock countries
- Low Income – Upper Middle-Income countries
- Hundreds of languages
- Different sizes and capacities of NRAs
  - India, Indonesia, Thailand: Maturity level 3 for vaccines regulation
- South-East Asia Regulatory Network

World Health Organization

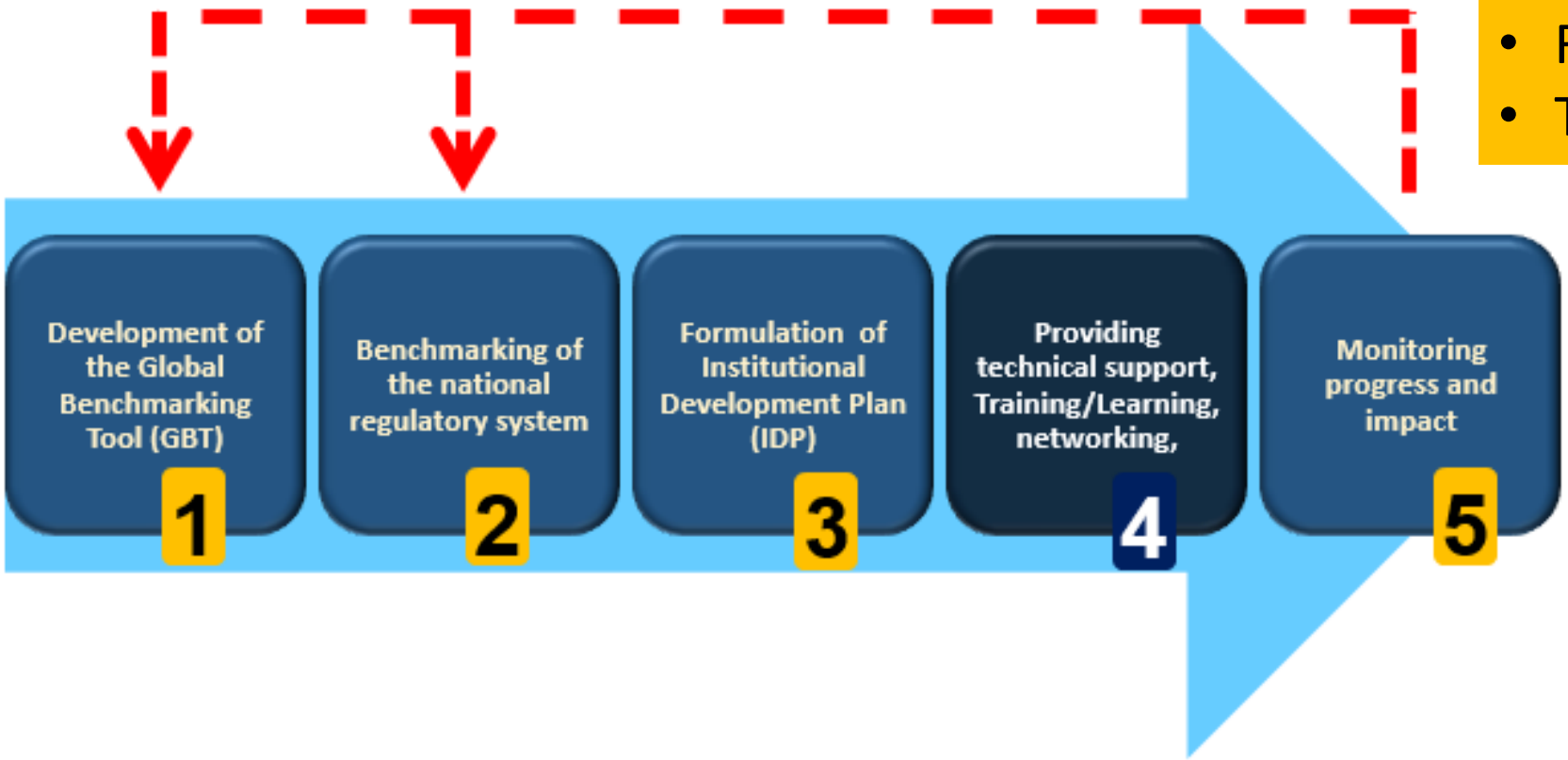
Regulatory systems: key issues/gaps in the region
(each country is unique)

1. **Leadership / political willingness**
2. **Legal provisions** and **autonomy**
   - Insufficient legal mandate
   - Insufficient sanctions
3. **Clear vision and objectives**
   - What does the NRA want to achieve in each function, with the available resources?
4. **Quality Management Systems**
5. **Human resources**
   - Number and competency (and how to document it)
6. **Cooperation between authorities**
   - Formal arrangements are required
   - Within and between countries

Key activities for regulatory strengthening

Regional office – close coordination with HQ, country offices and partners, focus on:

- Pre-benchmarking
- Follow up
- Targeted capacity building



- Stable, well functioning and integrated regulatory system
- Eligibility for vaccine PQ
- WHO listed authorities (WLA)

World Health Organization

Source: WHO HQ/REG/RSS

Key activities for regulatory strengthening

Support to Individual countries

- Technical recommendations
- Review of documents
- Training
- Advocacy
- Procurement
- Placement
- CIP initiated in two countries

Support to a group of countries:

- Workshops
  - System strengthening: preparedness, QMS, GMP, Laboratory testing
  - Specific needs: 2022 COVID-19, 2023 Contaminated medicines
- Collaboration to address common issues:
  - Secretariat of SEARN – early collaboration with partners, e.g. MTaPS
  - Support to small NRAs

World Health Organization

Approaches and opportunities for capacity development

- **Rely on existing capacities:**
  - From **NRAs**:
    - regional centres of regulatory excellence?
    - Regional collaboration: every NRA can contribute to common goals
  - **Partners**: Coalition of interested Parties to be further explored at national and regional levels
- **Address the needs of all Member States**
  - Addressing basic needs benefit all
  - Addressing advanced needs keep all engaged
  - Some basic needs require innovative solutions
- **Engagement with NRA stakeholders at the regional level**
  - Industry
  - Healthcare professionals
  - Procurement agencies
  - …
- **Keep the implementation in mind**
  - E.g. reliance requires access to information
    - Access to information requires sharing information
      - Sharing information requires…

Next steps

- Further develop Risk-based approaches to regulation
- Continue promoting NRAs' autonomy
- Continue supporting the development of SEARN
- Systematic approach to healthcare products:
  - Medical devices
  - Traditional products
  - Blood products
- New missions of NRAs?
  - shortages prevention, monitoring and management
- Strengthen collaboration with partners:
  - Develop CIP at the national level
  - Explore a CIP at SEARN level to support the Network

Resources

- Global Benchmarking Tool: Medicines, Vaccines, Medical devices, Blood products
- WLA framework
- CIP: cip-network-rss.org
- SEARN: searn-network.org
- Good reliance practices
- Good regulatory practices
- …

World Health Organization

Thank you

World Health Organization

REGULATORY WORKFORCE DEVELOPMENT FOR NATIONAL REGULATORY AUTHORITIES IN THE ASIAN REGION

Vivian Rakuomi
Senior Technical Advisor, Regulatory System Strengthening
MTaPS Program

Outline

- Overview of Medical Products Regulatory System
- Approach for NRAs Regulatory Workforce Development
- WHO Global Competency Framework Model
  - Competency framework and implementation tool
  - Summary of framework components
- MTaPS Approach
  - Methodology
  - Data Analysis
- Results Summary
- Recommendations and Lessons Learned

WHO Approach for NRA Strengthening

- The World Health Organization (WHO) Global Benchmarking Tool (GBT) provides a global metric **for measuring the functionality** and maturity of a regulatory system.
- Important to develop requisite knowledge, skills and attitudes of the NRA regulatory workforce to support the effectiveness and efficiency of the regulatory system for improved maturity level of NRAs.
- WHO developed a global competency framework that defines the knowledge, skills, attitudes, and behaviors needed for people within an NRA through education, training, and experience.

Overview of Medical Products Regulatory System

According to WHO a functional NRA should have several components:

Organizational

1. Legal provisions, regulations and guidelines
2. Organization and governance
3. Policy and strategic planning
4. Leadership and crisis management
5. Transparency, accountability & communication
6. Quality and risk management system
7. Regulatory process
8. Resources (HR, FR, experts, infrastructure, equipment & IMS)
9. Monitoring progress and assessing impact

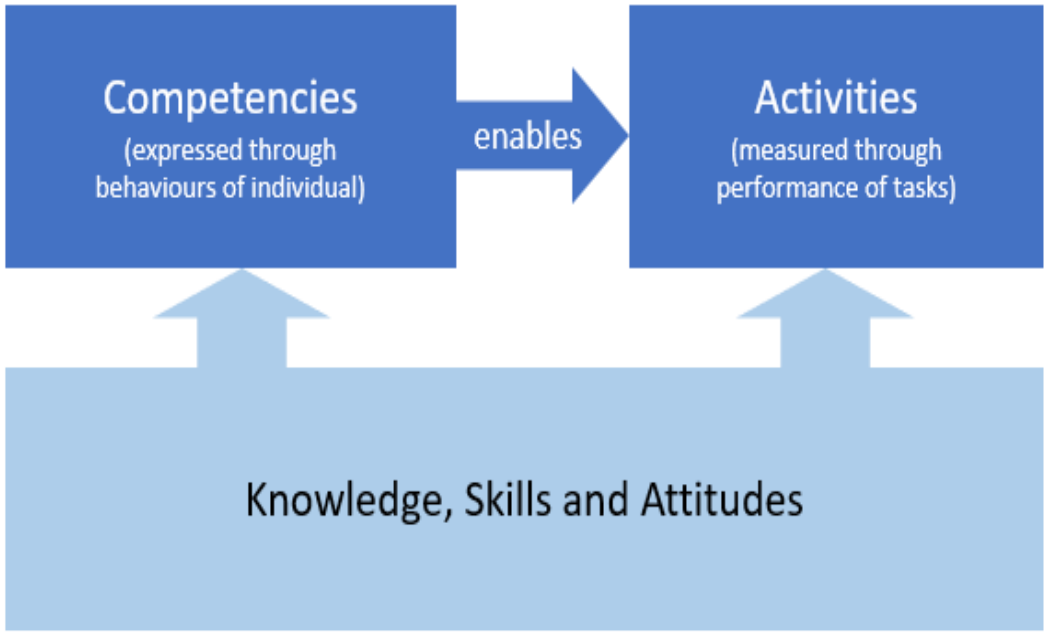
Technical

1. Product registration
2. Licensing of establishments
3. Market surveillance and control
4. Regulatory inspections
5. Vigilance
6. Clinical trials oversight
7. Laboratory inspections
8. Lot release

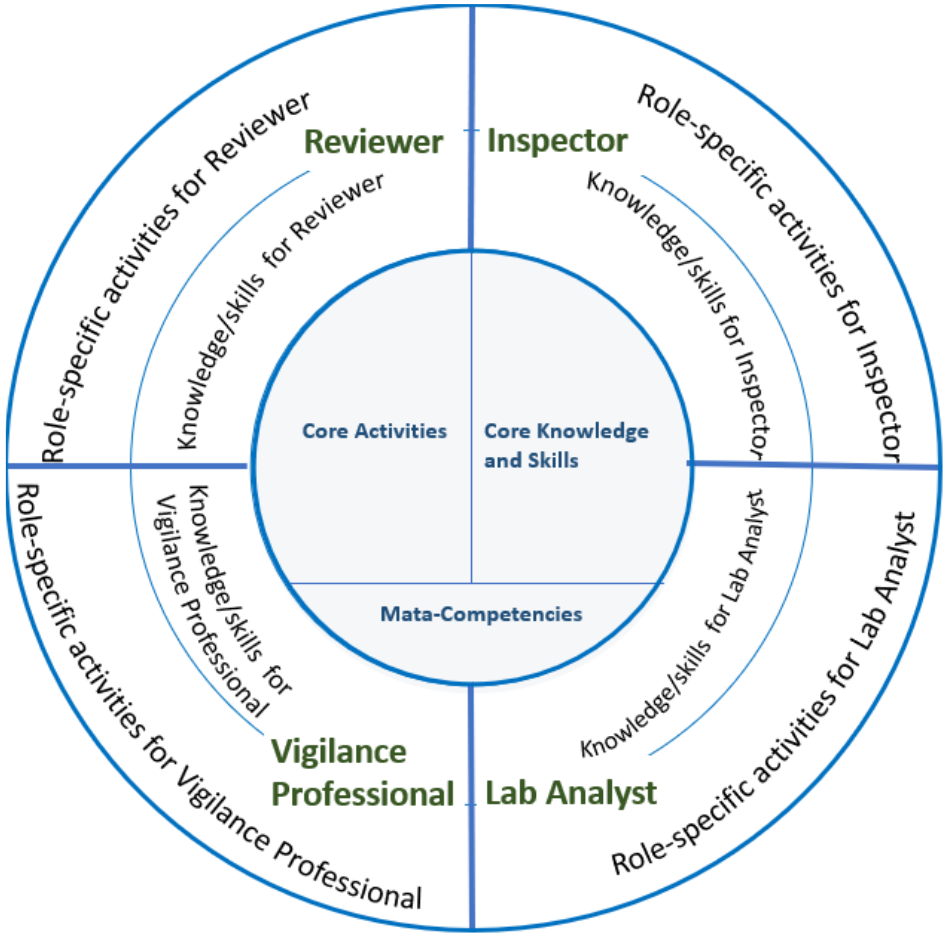
All these require critical knowledge, skills and attitude that enable NRAs to meet their obligations and mandate

WHO's Competency Framework Model

- Defines the required knowledge, skills, attitudes, and behaviors.
- Outlines recommendations for the competency requirements and training needs.
- Allows competency modeling by individual NRAs.



Competency Framework and Implementation Tool



Overview of Global Competency Framework for Regulators of Medical Products

Implementation tool

Competency Domain	Competency Description	Behavior Testimony	Response	Comments
Bioavailability / bioequivalence	Apply scientific principles, regulatory requirements, and best practices to review bioavailability and bioequivalence data.	Do you articulate the historical background to bioequivalence requirements?	☐ Yes ☐ No ☐ N/A	
		Do you Articulate the responsibilities of sponsors in a bioequivalence study?	☐ Yes ☐ No ☐ N/A	
		Do you Assess in vitro dissolution study protocols and reports/results in line with applicable regulatory requirements (WHO or Ich requirements)?	☐ Yes ☐ No ☐ N/A	
		Do you Describe the key principles in bioanalytical methods for the analysis of subject samples?	☐ Yes ☐ No ☐ N/A	
		Do you Discuss the key pharmacokinetic parameters in the demonstration of Bioequivalence?	☐ Yes ☐ No ☐ N/A	
		Do you Explain the basic principles of equivalence and its application in BE studies?	☐ Yes ☐ No ☐ N/A	
		Do you Explain the basic principles of equivalence and its application in BE studies?	☐ Yes ☐ No ☐ N/A	
		Do you Explain the critical	☐ Yes ☐ No ☐ N/A	

Summary of Framework Components

Organizational requirements

Meta-competencies: communication, compliance, critical and analytical thinking, evidence-informed practice, lifelong learning, operating with integrity, problem-solving, production of results, and teamwork.

Core organizational activities: leadership; organizational awareness; preparation of reports to support regulatory decisions; quality management system (QMS); regulatory framework, policies, and process; surveillance and enforcement; and talent development.

Core knowledge and skills: knowledge and skills that support the core activities aligned to each regulatory function and that are specific to that function.

Functional competencies: statutes, regulations, guidelines, and processes, supervision of others, quality management system, regulatory inspections, and product quality.

Role-specific requirements

Role-specific activities: tasks that are specific to a regulatory role, which contribute to the NRA's regulatory functions

Role-specific knowledge and skills: knowledge and skills that underpin the performance of role-specific practice activities

MTaPS Technical Approach

- MTaPS, in collaboration with the NRAs of Bangladesh, Nepal, and The Philippines, identified key regulatory areas and undertook competency mapping aligned to each country's needs.
- Assessed workforce competency of regulatory reviewers, inspectors, vigilance personnel, and analysts to:
  - Identify critical skills and competency gaps of NRA staff in Bangladesh, Nepal, and the Philippines.
  - Establish framework to identify training needs and formulate plans for NRAs to meet a higher maturity level.
  - Guide training (academic and on-the-job training) to ensure systematic professional development and recognition of regulatory staff.

Competency Assessment Methodology

Questionnaire sections

Sl. No.	Section*	Regulatory activities	What is covered
1	5.1	Practice activities – core	Organizational/ individual activities
2	5.2	Practice activities – reviewers	Specific role of dossier reviewers
3	5.3	Practice activities – inspectors	Specific role of inspectors
4	5.4	Practice activities – analysts	Specific role of analysts
5	5.5	Practice activities – PV	Pharmacovigilance
6	6.1	Meta competencies	Organizational/ individual activities
7	6.2	Functional competencies – regulators	Organizational/ individual activities
8	6.3	Role-specific competencies – inspectors	Specific role of inspectors
9	6.4	Role-specific competencies – reviewers/assessors	Specific role of reviewers/assessors
10	6.5	Role-specific competencies – PV	Pharmacovigilance
11	6.6	Role-specific competencies – analysts	Laboratory activity

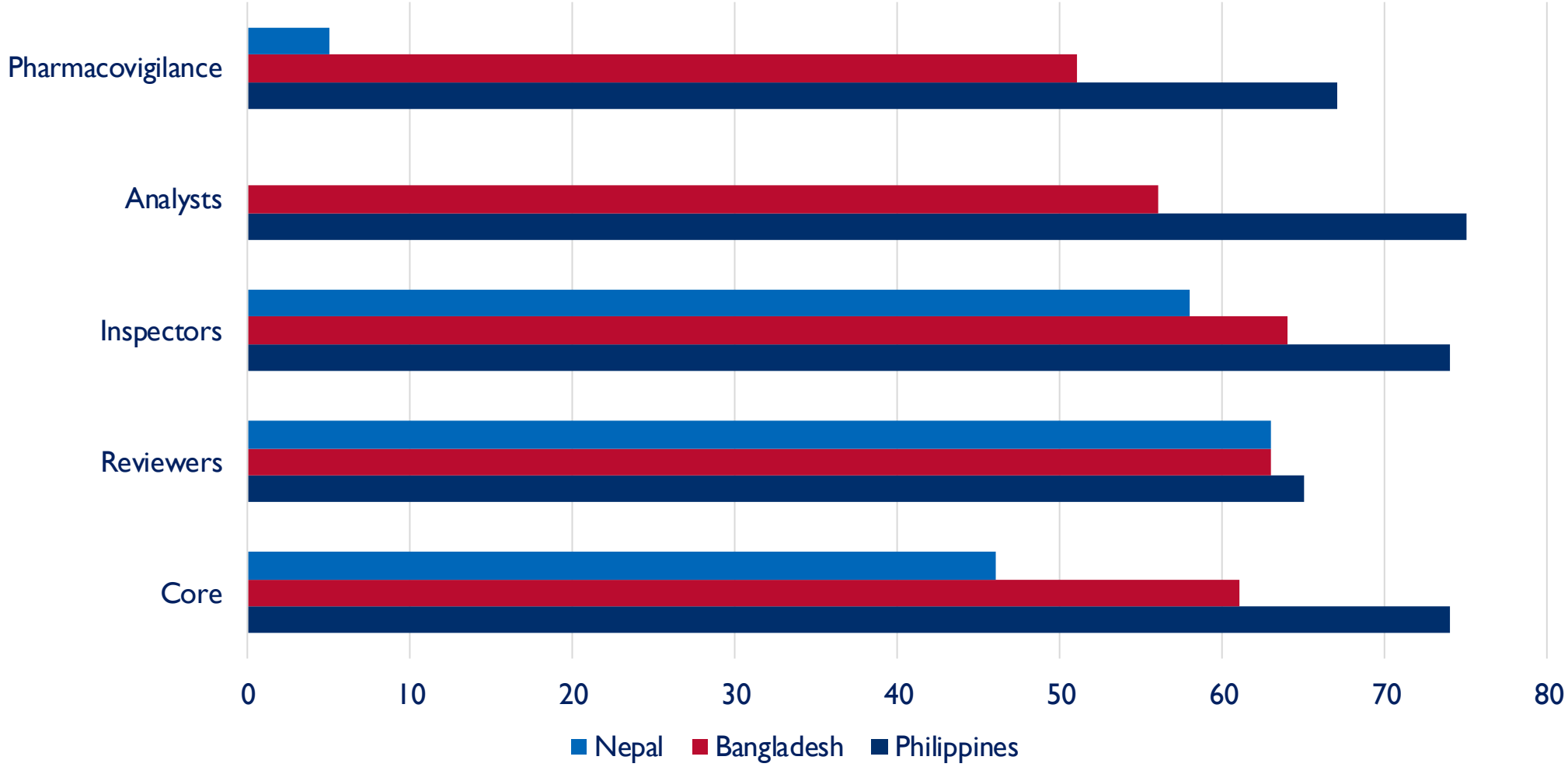
Target respondents for the questionnaire

Section	Respondents
Organizational competencies	
5.1. Practice activities - CORE	CEO and Directors
6.1. Meta competencies	Department/Unit heads
6.2. Functional competencies	Department/Unit heads
Role Specific competencies	
5.2, 5.3,5.4. Practice Activities	Departments/units heads/staff
6.3,6.4,6.5. Role-specific competencies	Departments/units heads/staff

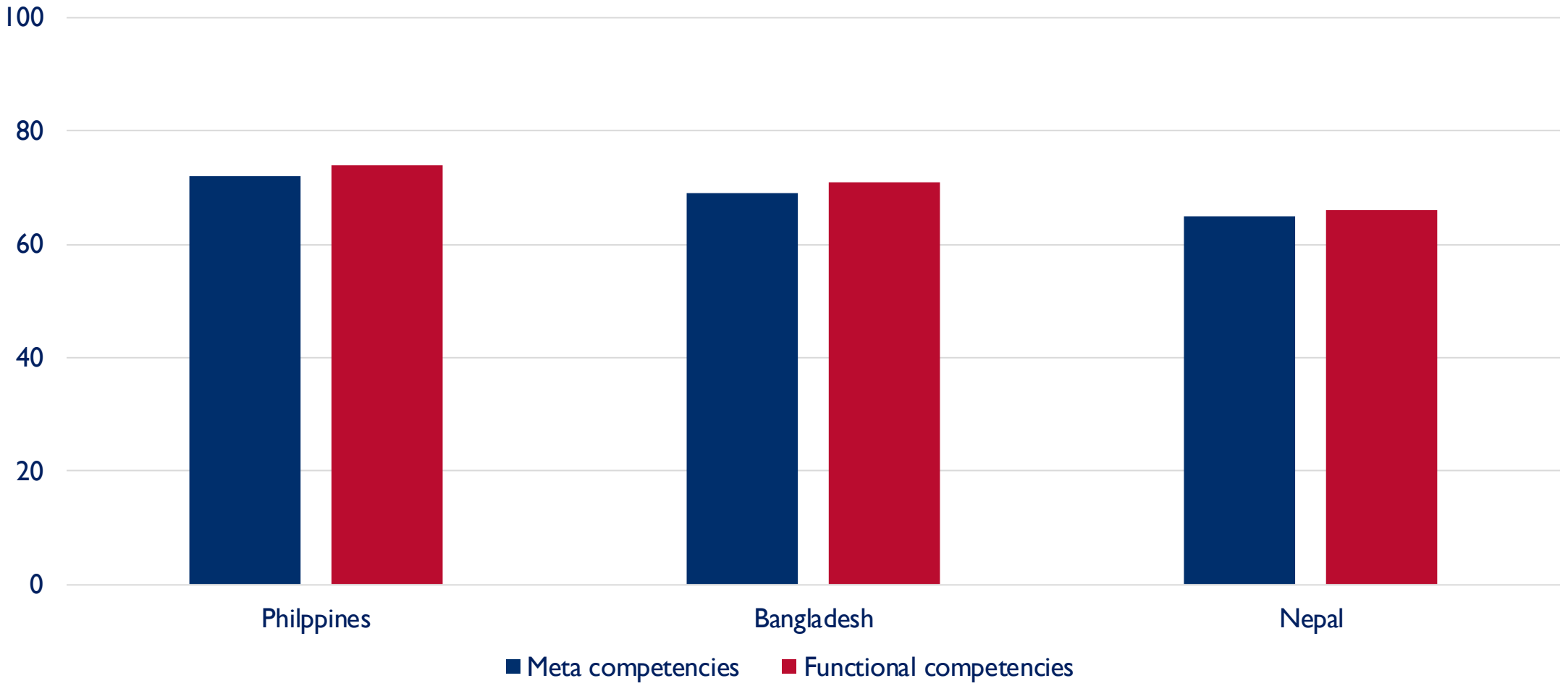
Data Analysis

Sl. No.	Proficiency Level	Assigned number	Activity achievement score	Assigned number	Lowest Score	Highest Score
1	Foundation	3	Initiated/preliminary stage	1 - 3	3	9
			Partially implemented	4 - 6	12	18
			Implemented/in practice	7 - 10	21	30
2	Intermediate	6	Initiated/preliminary stage	1 - 3	6	18
			Partially implemented	4 - 6	24	36
			Implemented/in practice	7 - 10	42	60
3	Advanced	9	Initiated/preliminary stage	1 - 3	9	27
			Partially implemented	4 - 6	36	54
			Implemented/in practice	7 - 10	63	90

Results and Findings



Results: Organizational Competency



Summary of Results

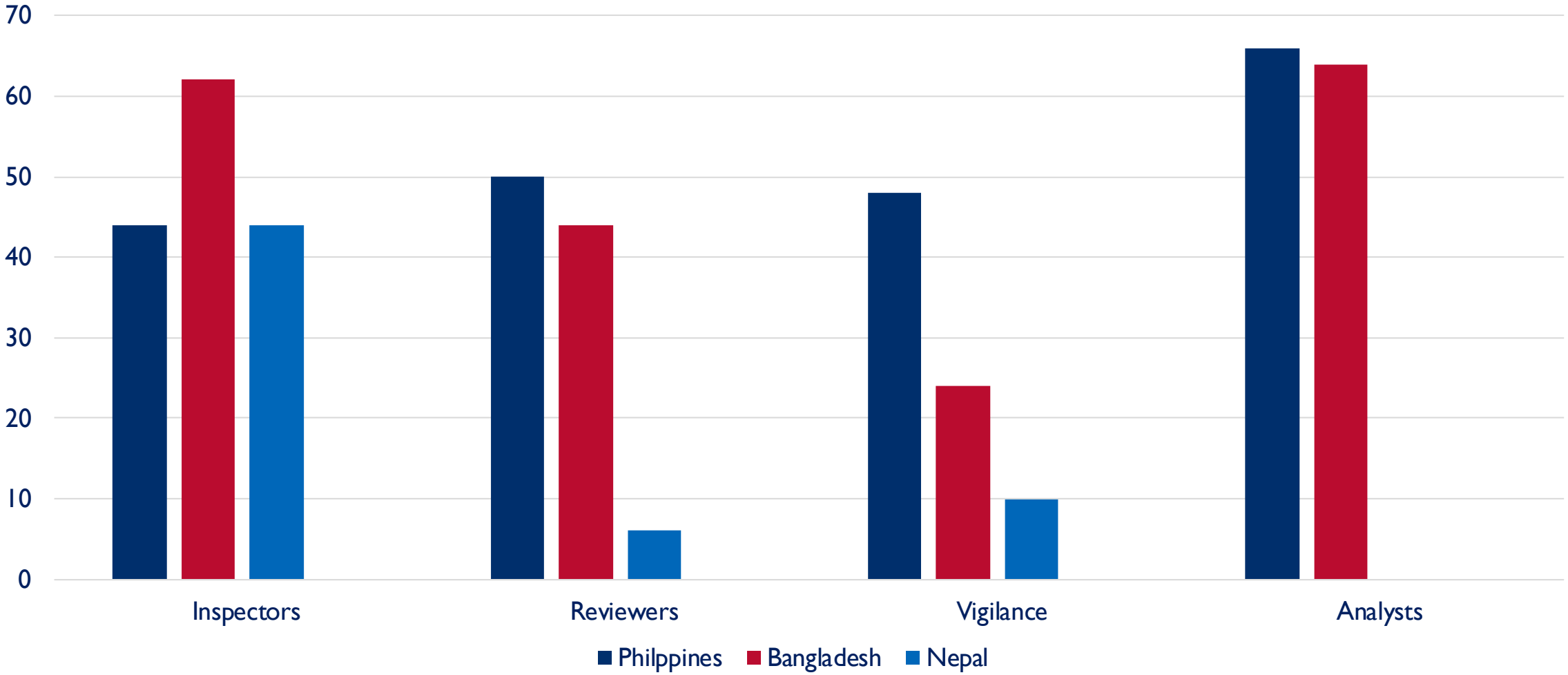
Core competencies: Countries exhibited appreciable practices related to organizational competencies including leadership and regulatory legal framework. Improvements are needed in the delegation of the authority, management information system, and implementing the QMS.

Meta-competencies: There is need to adopt international best practices, development of and implementation of sound guidelines, and procedures as well as continuous professional development and quality improvement, access to sources of information including tools, journals, publications.

Functional competences: Need to improve in applying the quality management system, surveillance and enforcement and taking appropriate regulatory action to ensure compliance and to protect public health.

Role specific: Despite a favorable attitude and grasp of the regulatory process there are gaps in the PV (risk management/signal detection), reviewer's (bioequivalence studies and safety data reviews), inspectors (clinical study operations and investigational product development), analyst (verification of analytical reports, performance of mathematical manipulations).

Results: Role Specific Activities



Recommendations

NRAs	Identify opportunities for skills development based on the outcomes identified by mapping exercises i.e implementation of training plans.
	Continue to build strong foundations in regulatory competency by implementing WHO GBT indicators while collaborating with other organizations, and planning for the short, middle, and long-term capacity strengthening plans
	Competency mapping exercise should be an ongoing metric within the NRAs to increase the technical knowledge and skills of their staff.
Regional networks	Develop a regional capacity-building guidance document for countries to adopt and implement.
	Regulatory harmonization and reliance mechanisms are good ways of assisting NRAs to meet their regulatory obligations and should be explored.

Resources

- WHO Global Benchmarking Tool
- WHO Competency Mapping Framework and Implementation Tool

MINIMUM COMMON STANDARDS FOR REGULATORY INFORMATION MANAGEMENT SYSTEMS

Kate Kikule, Principal Technical Advisor – PRS, USAID MTaPS Program

Souly Phanouvong, Technical Director, USAID PQM+ Program

Context

- NRAs promote access to quality-assured, safe and efficacious medicines and combat substandard or falsified medical products.
- Capacity in LMICs is insufficient, inefficient regulatory workflows exist, lack of transparency, mismanagement, and vulnerability to corruption.
- NRAs have initiated digitalization to improve consistency, efficiency, and accountability in regulatory services, and to facilitate convergence and harmonization within and between NRAs.

The USAID-funded MTaPS and USAID-funded PQM+ programs engaged global stakeholders and subject matter experts to identify and recommend a set of minimum common standards (MCSs) for regulatory information management systems (IMSs)

Overview of Regulatory Information Management Systems

- Standards in this context refer to the basis of measure, norms, and guidelines for regulatory IMS that would enable uniform data capture, a standardized data exchange platform and workflow of digitalized regulatory functions, leading to efficiencies and enhanced governance.

- IMS serve as tools to facilitate effective functioning and performance of regulatory processes.

- Regulatory IMS were structured around the eight regulatory functions outlined in the WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems: registration and marketing authorization, vigilance, market surveillance and control, licensing establishments, regulatory inspection, laboratory testing, clinical trials oversight, and NRA lot release.

Challenges

- In many LMICs, the regulatory IMS that support the key functions are disjointed and poorly managed, not interoperable with other systems within or among countries In some cases, digitalized regulatory IMS are nonfunctional or nonexistent.

- Many regulatory processes are still paper based leading to inefficient and inconsistent workflows and increased likelihood of human errors in data management, backlogs and delays, lack of transparency, and corruption.

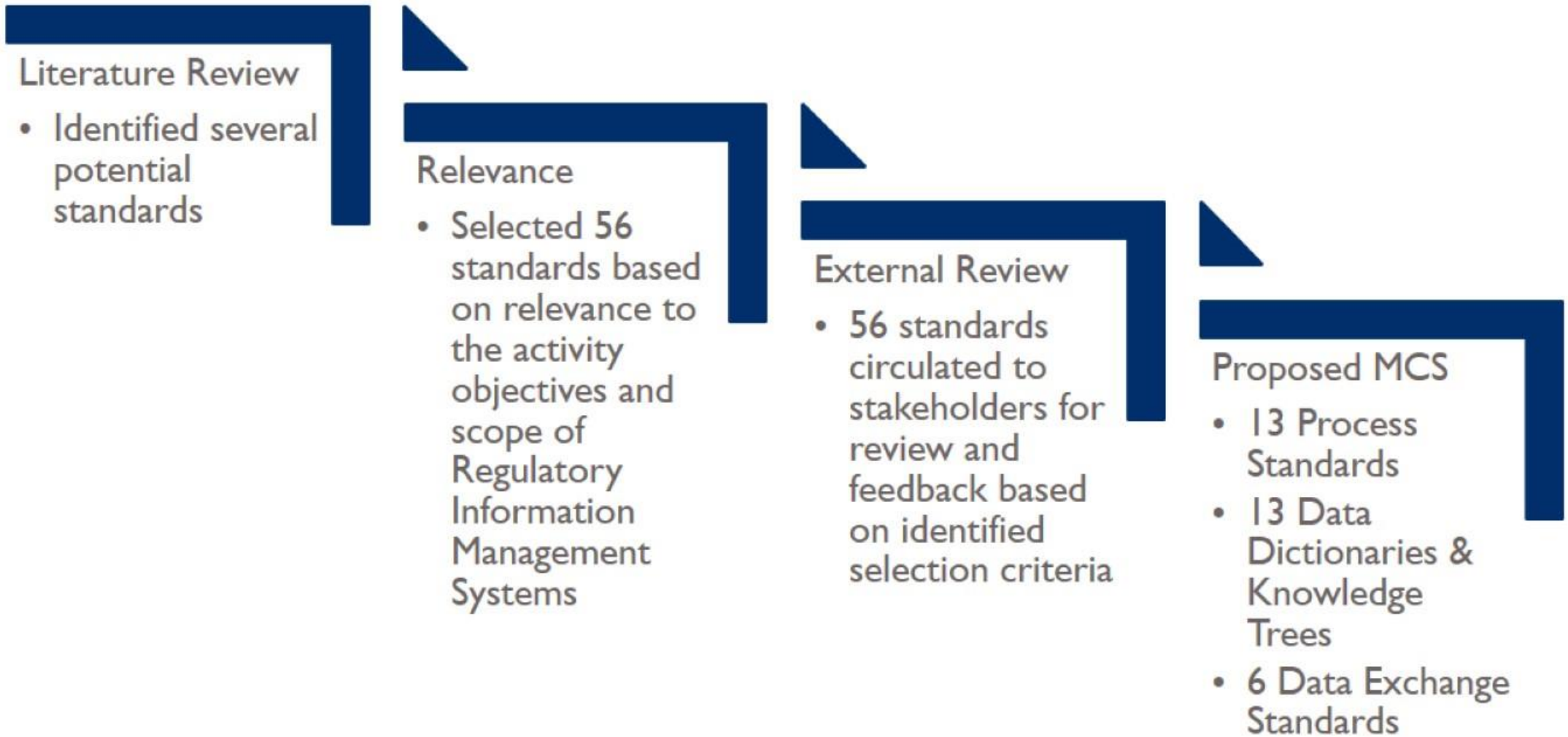
- NRAs struggle to fully operationalize both web- and paper-based IMS, which limits the availability of real-time data.

- Some countries are addressing these challenges by digitalizing regulatory IMS, but the variation in approaches to digitalization exacerbates issues of interoperability and complicates collaboration among NRAs.

MCS Development Process

- Identified the critical gaps and challenges NMRAs and other stakeholders are facing with regulatory IMS.
- Derived a recommended set of minimum common standards for regulatory IMS.
- Developed the use case for the minimum common standards.
- Promoted their adoption and use in digitalization of Regulatory IMS.

Standards Selection Process



Categories of Standards

Desk review and relevance selection yielded 56 standards, grouped into 3 categories:

1) Process or workflow standards

- Apply to pharmaceutical:
  - Procedures
  - Processes
  - Workflows

Examples:

- Good practices (GXPs such as Good Manufacturing Practices (GMP)
- International Organization for Standardization standards (ISOs) such as ISO 9001:2015

15 standards identified

2) Pharmaceutical standard dictionaries and knowledge trees

- Master or reference lists for:
  - Terminology
  - Nomenclature
  - Hierarchies

Examples:

- Anatomical Therapeutic Chemical (ATC)
- International Nonproprietary Name (INN)

21 standards identified

3) Data exchange standards

Pertain to:

- Information and communications technology
- Management information system functions
- Determine how data should be structured, defined, formatted

Examples:

- Common Technical Document (CTD) format
- Extensible Markup Language (XML)
- Platforms such as Fast Health Interoperability Resources (FHIR®)

20 standards identified

Selection Criteria

1

Relevance—the standard should be critical for at least one of the eight core regulatory functions as defined in the WHO GBT v2.0

2

Feasibility—the extent to which NMRAs' capacity and resources feasibly allow adoption and what are the anticipated efficiency gains

3

Criticality—what would countries benefit or lose by not applying a given standard

4

Universality—whether a given standard is recommended by WHO and extent to which it is widely used

Number of resulting standards per category after analysis

1) Process or workflow standards

Apply to pharmaceutical:

- Procedures
- Processes
- Workflows

15 standards initially identified

13 remaining in the proposed MCS list.

2) Pharmaceutical standard dictionaries and knowledge trees

Master or reference lists for:

- Terminology
- Nomenclature
- Hierarchies

21 standards initially identified

13 remaining in the proposed MCS list.

3) Data exchange standards

Pertain to:

- Information and communications technology
- Management information system functions
- Determine how data should be structured, defined, formatted

20 standards initially identified

6 remaining in the proposed MCS list.

Complete Set of Recommended Standards (Sorted by **Feasibility**)

Process Standards

- Good Laboratory Practices (GLP)
- Monographs
- ISO 9001:2015 - Quality Management System Procedures
- Good Distribution Practices (GDP)
- ISO 17025:2017
- Good Practices For Pharmaceutical Quality Control Laboratories
- Good Clinical Practice (GCP)
- Good Manufacturing Practices (GMP) or ICH Q7
- Good Practices For Pharmaceutical Microbiology Laboratories
- Good Review Practices (GRevP)
- Good Storage Practices (GSP)
- ICH Q10
- Good Pharmacovigilance Practices

Data Dictionaries and Knowledge Trees

- International Nonproprietary Names (INN)
- National Drug Code (NDC)
- Anatomical Therapeutic Chemical Index (ATC)
- WHODrug Global
- The Medical Dictionary for Regulatory Activities (MedDRA)
- Chemical Abstracts Service (CAS) registry number
- Unique Ingredient Identifier (UNII)
- ISO 11240 Units of Measurement (UoM)
- ISO 11239 Dosage Form and Route of Administration
- ISO 11616 Pharmaceutical Product Identifier (PhPID)
- ISO 11238 Substance Identification (SubID)
- GS1 Standards
- ISO 11615 Medicinal Product Identification (MPID)

Data Exchange Standards

- Portable Document Format (PDF)
- XML
- Common Technical Document (CTD)
- E2B - Pharmacovigilance: Individual Case Safety Reports (ICSR) or ISO/HL7 27953-2:2011
- Structured Product Labelling (SPL)
- Fast Healthcare Interoperability Standards (FHIR)

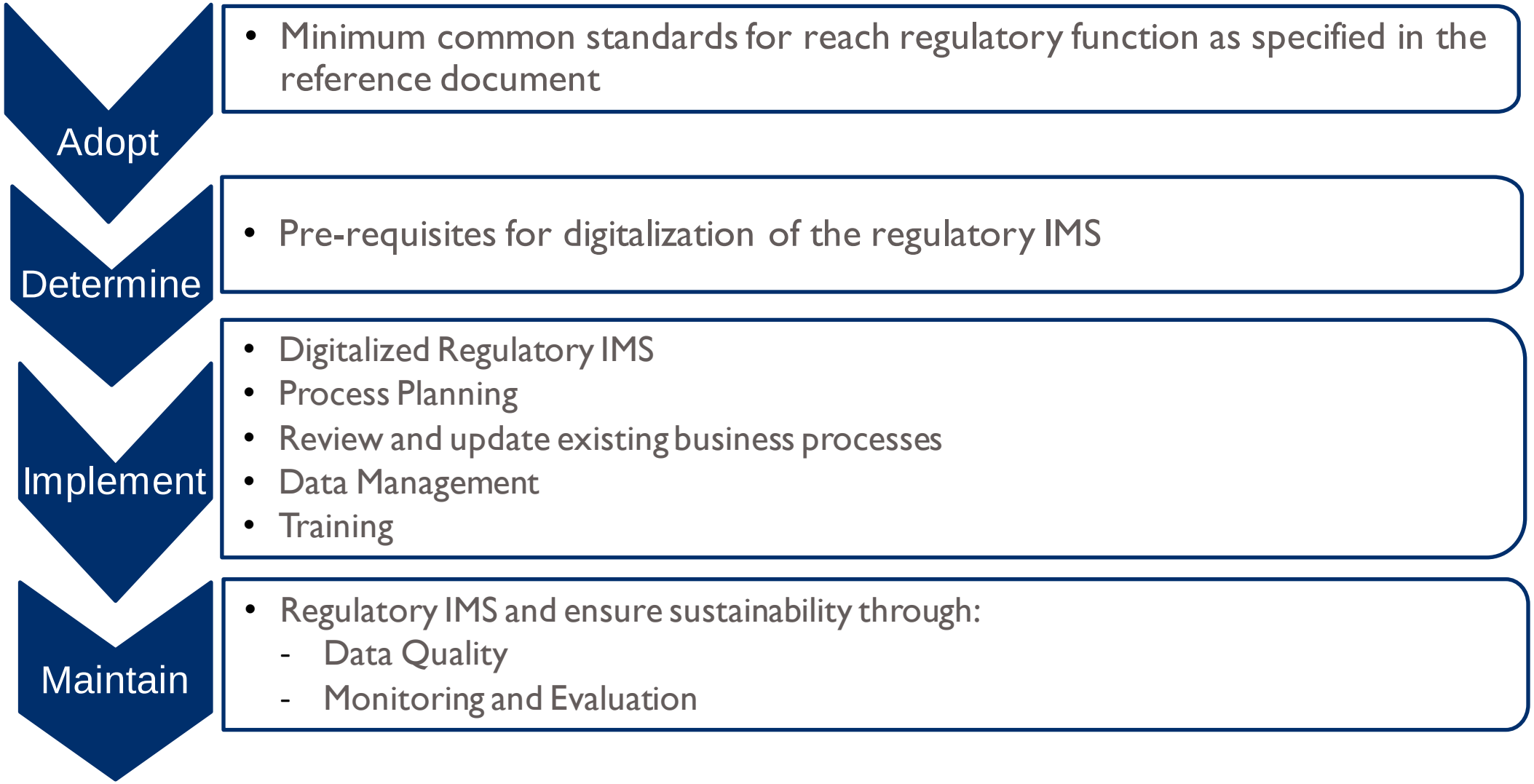
Benefits of Regulatory IMS to NRAs

- More efficient internal operations, such as workflow management, performance tracking, and reporting, which lowers the cost of running a RIMS.
- Expedited product assessments and facility inspections that deliver to the market prompt access to safe, high-quality medical products.
- Easy sharing of information about regulated medical products that may influence the health of the population, particularly regarding substandard and falsified medicines.
- Facilitated convergence and harmonization of regulatory services both within and outside of an NRA.
- Interoperability with the international systems with which LMIC national systems must communicate.
- Creation of a common language for system design and architecture that software developers can use to design information management system software for regulatory functions and make ents to existing digitalized systems.

Adoption and pathways for implementation of minimum common standards

- Adopt the minimum common standards for reach regulatory function as specified in the reference document
- Determine the pre-requisites for digitalization of the regulatory IMS
- Implement a digitalized Regulatory IMS
  - Process Planning
  - Review of Business Processes
  - Data Management
  - Training
- Maintenance and Sustainability
  - Monitoring and Evaluation

Adoption and pathways for implementation of minimum common standards



Call to Action

- Recognize and adopt the identified set of minimum common standards for regulatory IMS and provide international guidance and support from development partners to help countries implement the standards in their efforts to digitalize their regulatory IMS.
- The MCS work was presented to the newly Established WHO committee at the first WHO meeting of the Drafting Group of the WHO's guideline on RIMS. The WHO committee committed to leverage MCS documents to develop its own recommendations.
- Countries should be encouraged and supported to adopt these minimum common standards to align their regulatory processes with international best practices and guide digitalization of regulatory functions.
- We have produced three documents as part of the activity to sensitize countries and implementing partners to the standards, advocate for their use, and guide their integration within broader regulatory digitalization efforts.

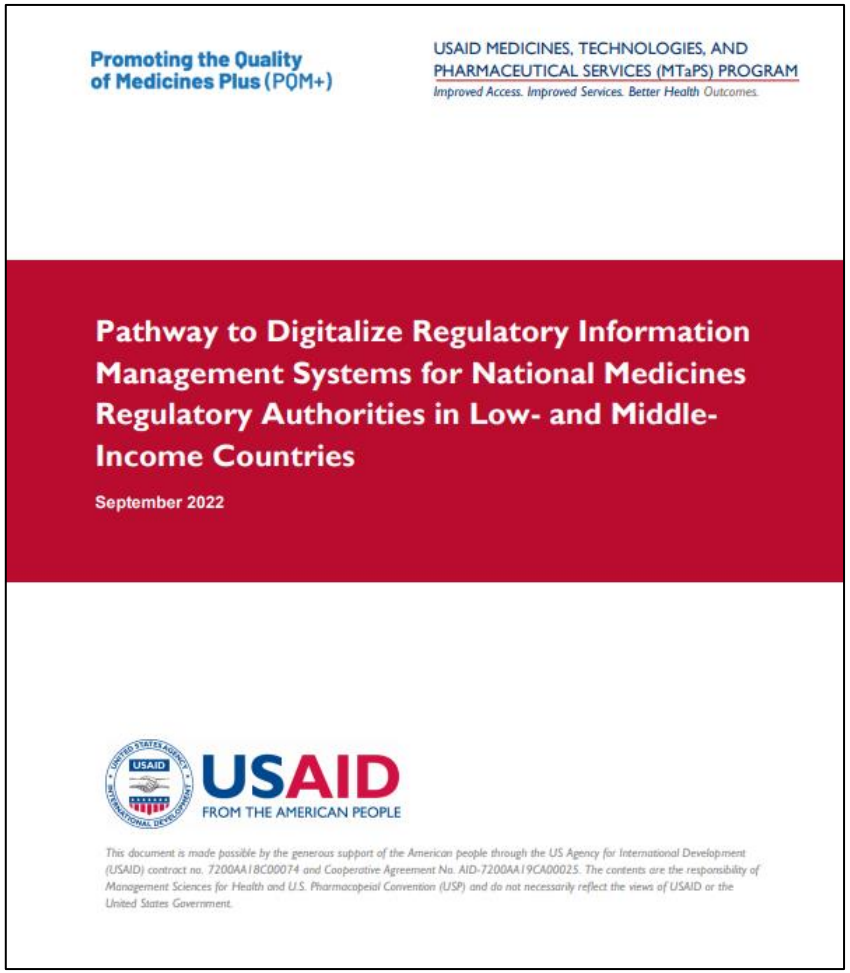
Adopting Minimum Common Standards for Regulatory Information Management Systems – A Call to Action

Advocacy brief providing an overview of:

- Current situation of pharmaceutical regulation in LMICs and harmonization efforts
- Justification for minimum common standards for regulatory IMS
- Obstacles to adopting minimum common standards
- Stakeholder call to action

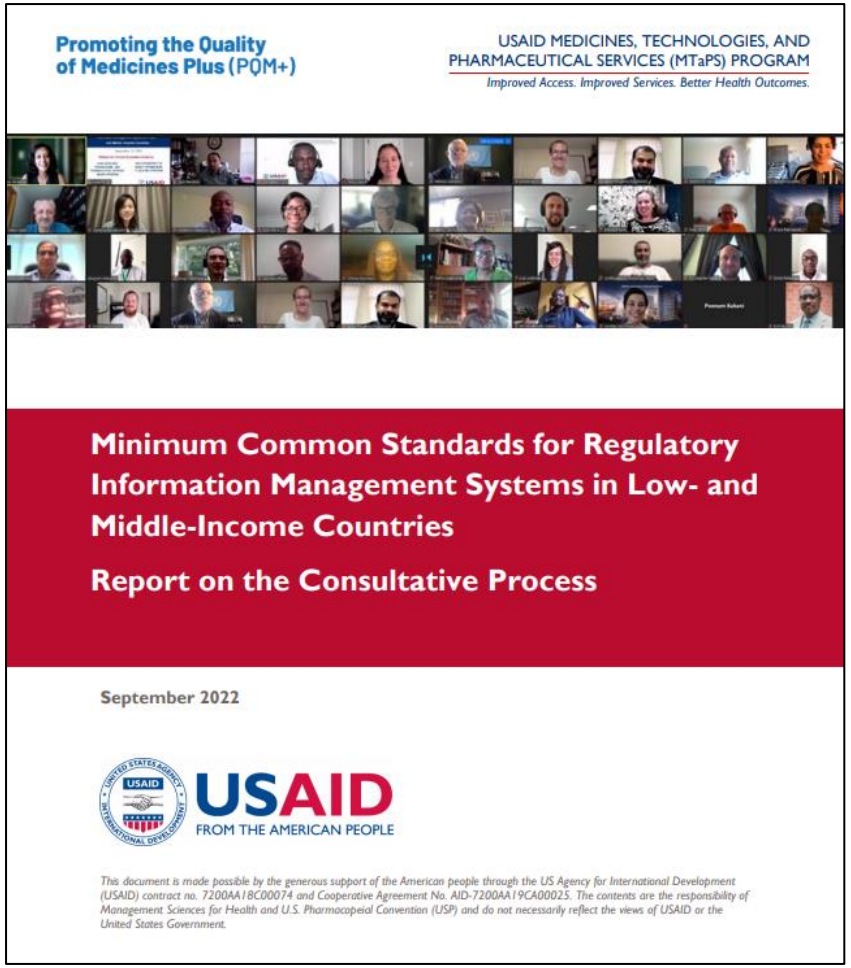
Pathway to Digitalize Regulatory Information Management Systems for National Medicines Regulatory Authorities in Low- and Middle-Income Countries

- Introduces the selected set of minimum common standards
- Provides summary of regulatory digitalization processes
- Overview of implementing digitalization in view of the standards and includes resources for more in depth guidance for each step



Report on the Consultative Process

- Introduces the selected set of minimum common standards
- In depth review of the selection process and criteria
- Overview of consultative process and detailed meeting reports



Publications

All publications can be found on the MTaPS program website.

USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program

Prime: Management Sciences for Health (MSH)

COR: Alexis Leonard, aleonard@usaid.gov

Learn more: www.mtapsprogram.org

USAID Promoting the Quality of Medicines (PQM+) Program

Prime: U.S. Pharmacopeia (USP)

AOR: Alison Collins, alcollins@usaid.gov

Learn more: www.usp.org/global-public-health/promoting-quality-of-medicines

Thank You

STRENGTHENING PHARMACEUTICAL REGULATORY SYSTEMS IN THE ASIAN REGION

Deane Putzier, Senior Principal Technical Advisor, MIS, MTaPS Program

About OpenRIMS

- OpenRIMS is also formerly known as Pharmadex.
- Web-based tool that helps NMRAs streamline.
- Track medicines registration to ensure that they have the most updated medicines available and approved for prescribing and use.

With OpenRIMS, NMRAs can:

Record and organize information

Track applications in the registration process

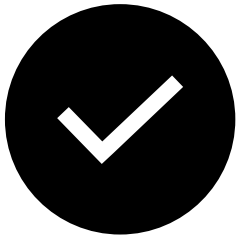
Analyze and compare multiple options

Track critical information for decision making, such as cost, usage, and safety

Use of OpenRIMS

ONLINE APPLICATION

APPLICATION TRACKING



APPLICATION STATUS UPDATE OVER EMAIL

ADVANCED QUANTITATIVE AND ANALYTICAL REPORTING

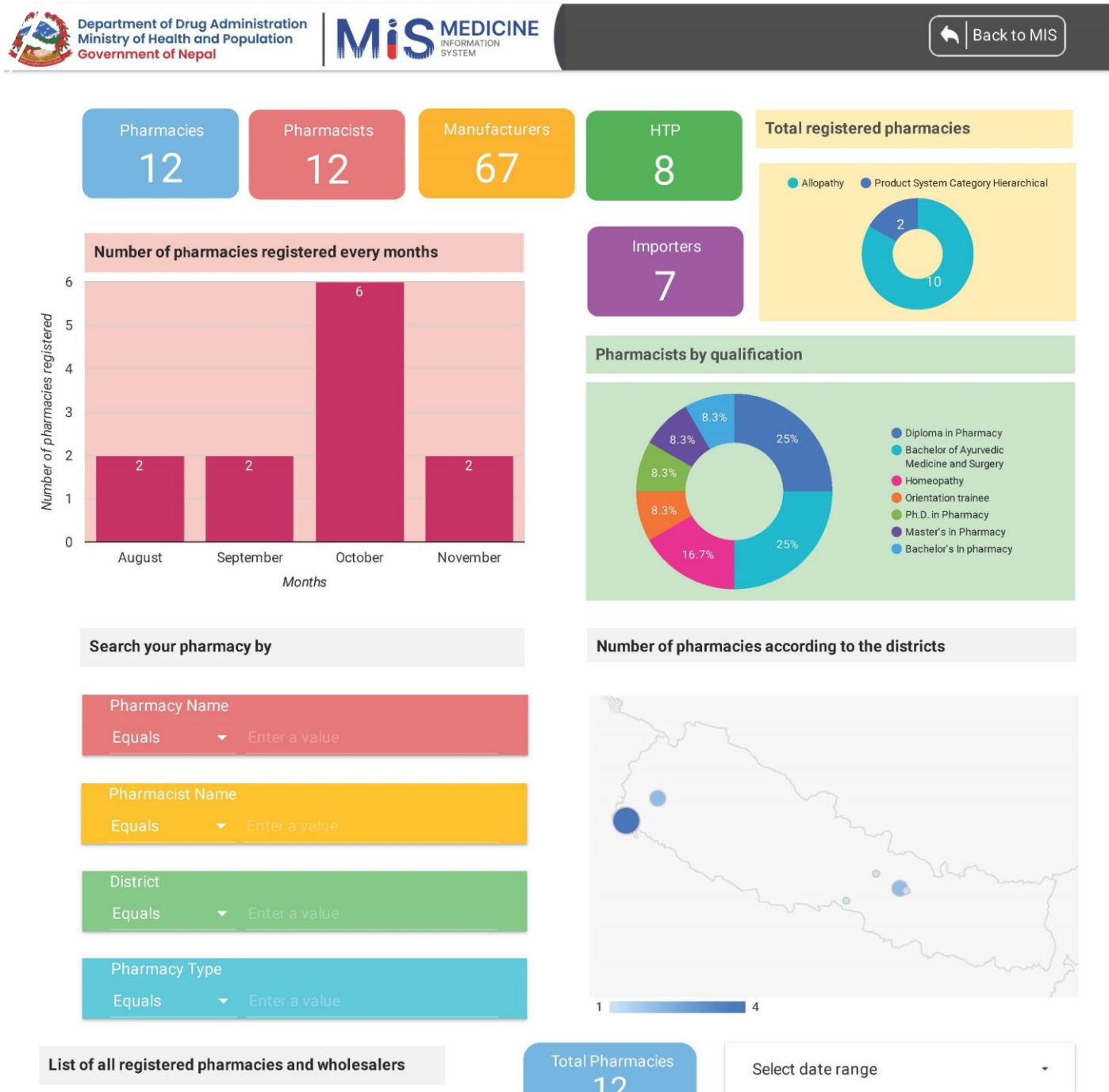
PERFORMANCE TRACKING OF DDA

Nepal - Problem Statement

- Lack of international standards like ATC, INN, WHO benchmarking
- Static development, heavy dependency on developer
- Poor user management feature
- Monolingual system
- No GIS feature
- Limited reporting module
- Limitation of physical server
- Lack of online payment feature
- Applicant's physical presence at DDA during the process

How OpenRIMS solves it?

- Includes the international standards as part of the system
- Easy customization of workflow, little or no dependency on changing the workflow design
- Better user, role and permission management
- Bilingual system
- GIS feature
- Reporting module
- Online payment system
- Digital signature

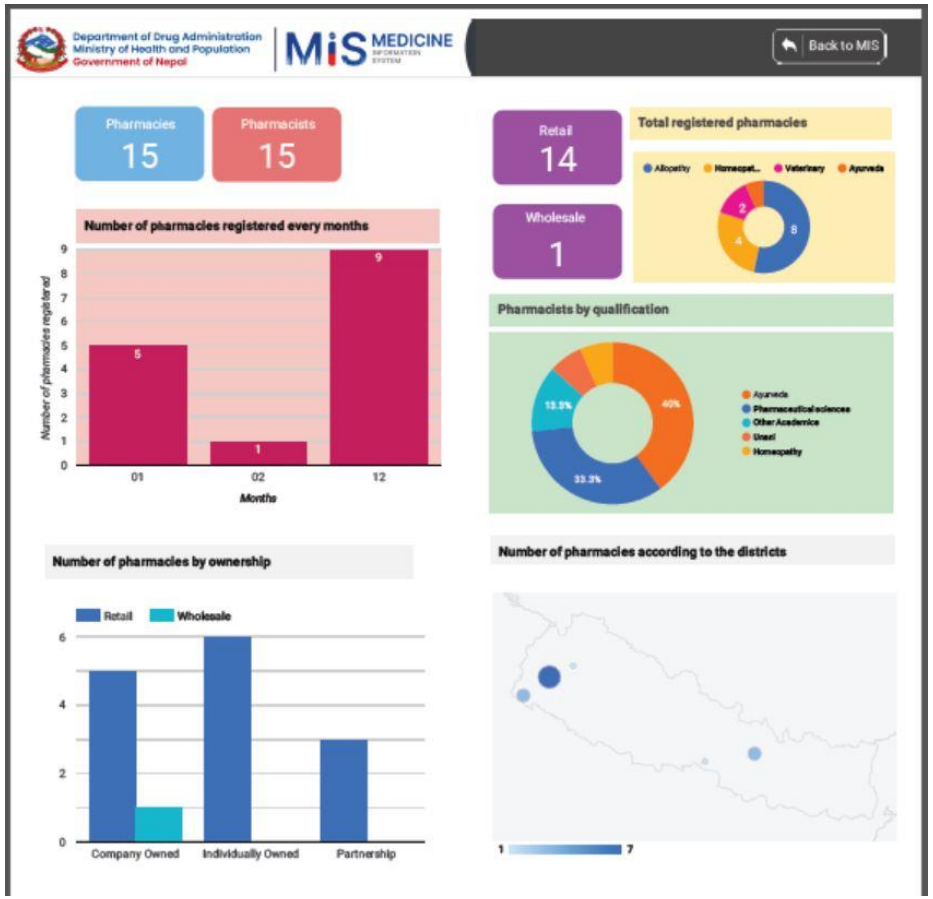


Outcome

- Improved accuracy and efficiency
- Increased transparency and accountability
- Improved accessibility
- Better data management
- Increased security
- Informed decision-making
- Cost savings

Progress on activity

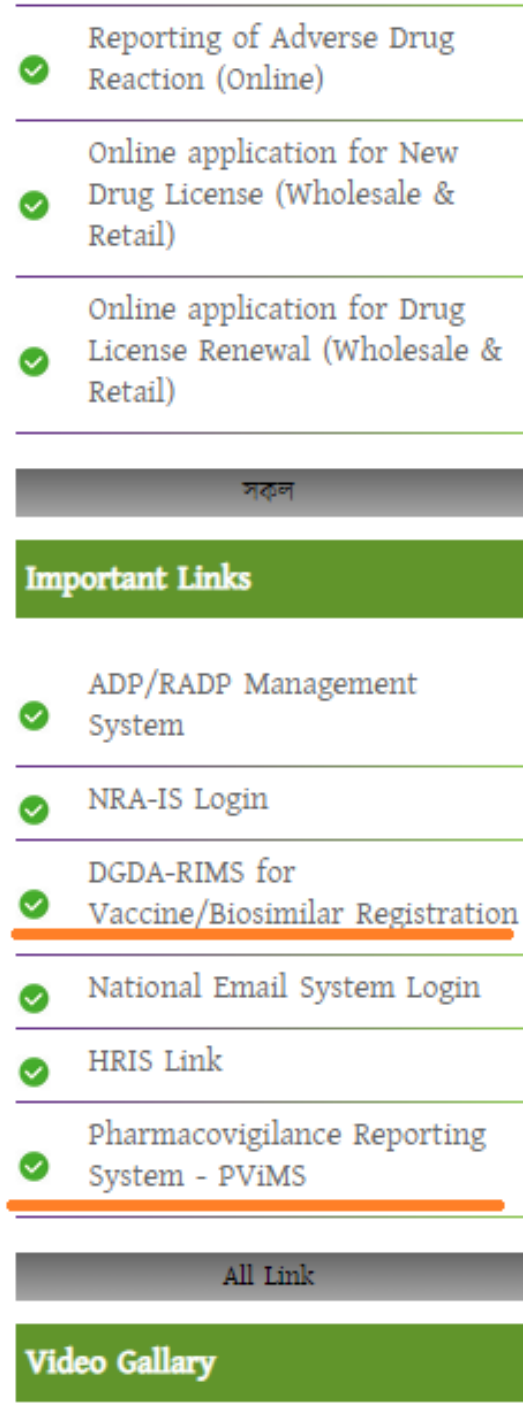
- Developed pharmacy and wholesaler registration module
- System audit by DOIT government of Nepal
- Production server deployed in NITC server (mis.dda.gov.np)
- UAT of Pharmacy and Wholesale registration module
- Developed Google Data Studio report
- Tools like image cropper and pharmacy name checker developed and deployed (apps.dda.gov.np)



Bangladesh

- Went "live" with the OpenRIMS Registration module.

- Vigilance module PViMS(OpenPV).
  - Refining PViMS with a localized development.



Bangladesh

- DGDA official website links:
  - http://dgda.gov.bd/
  - http://pv.dgda.gov.bd/
- PV activity
  - By the first week
    - 10 official Yellow Card submissions

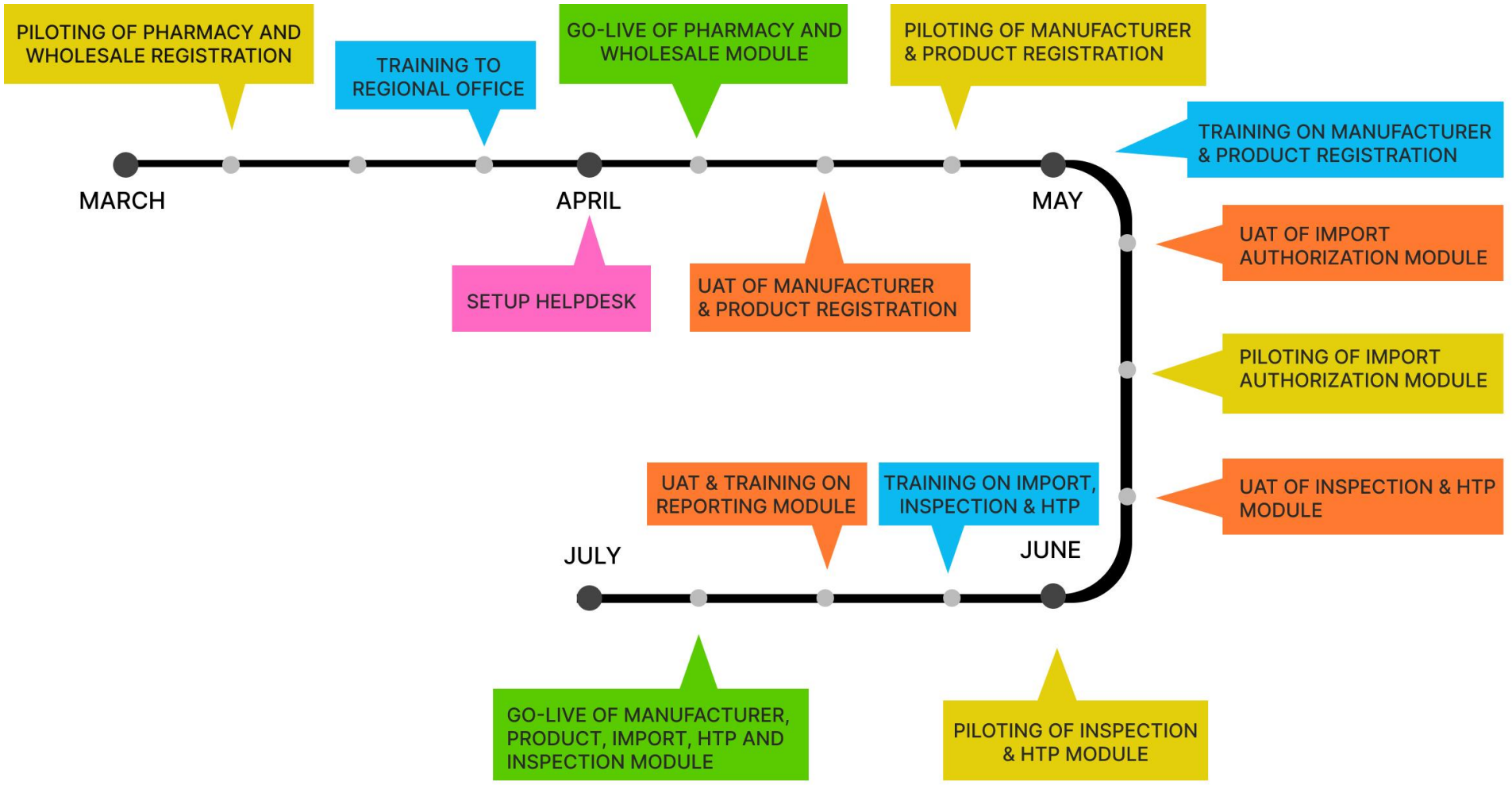
Challenges & risks

- Expectation management and handle change requests
- Adopting OpenRIMS as a standard system while incorporating local requirements
- Compete the feature with existing system and other government online systems
- Data (real and institutional) migration from existing system
- System Integration with other related government authorities
- Resistance to change
- Time constraints

Way forward

- Integrate online payment and digital signature
- Setup helpdesk and hire helpdesk officers
- Hire local vendors for long term support
- Conduct training of stakeholders at regional offices
- Finalize and conduct the User Acceptance Testing (UAT) of Manufacturer module, Product module, Importer module and Inspection module

Implementation plan



Q&A

CLOSING

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