Shared responsibilities for an end-to-end health product management

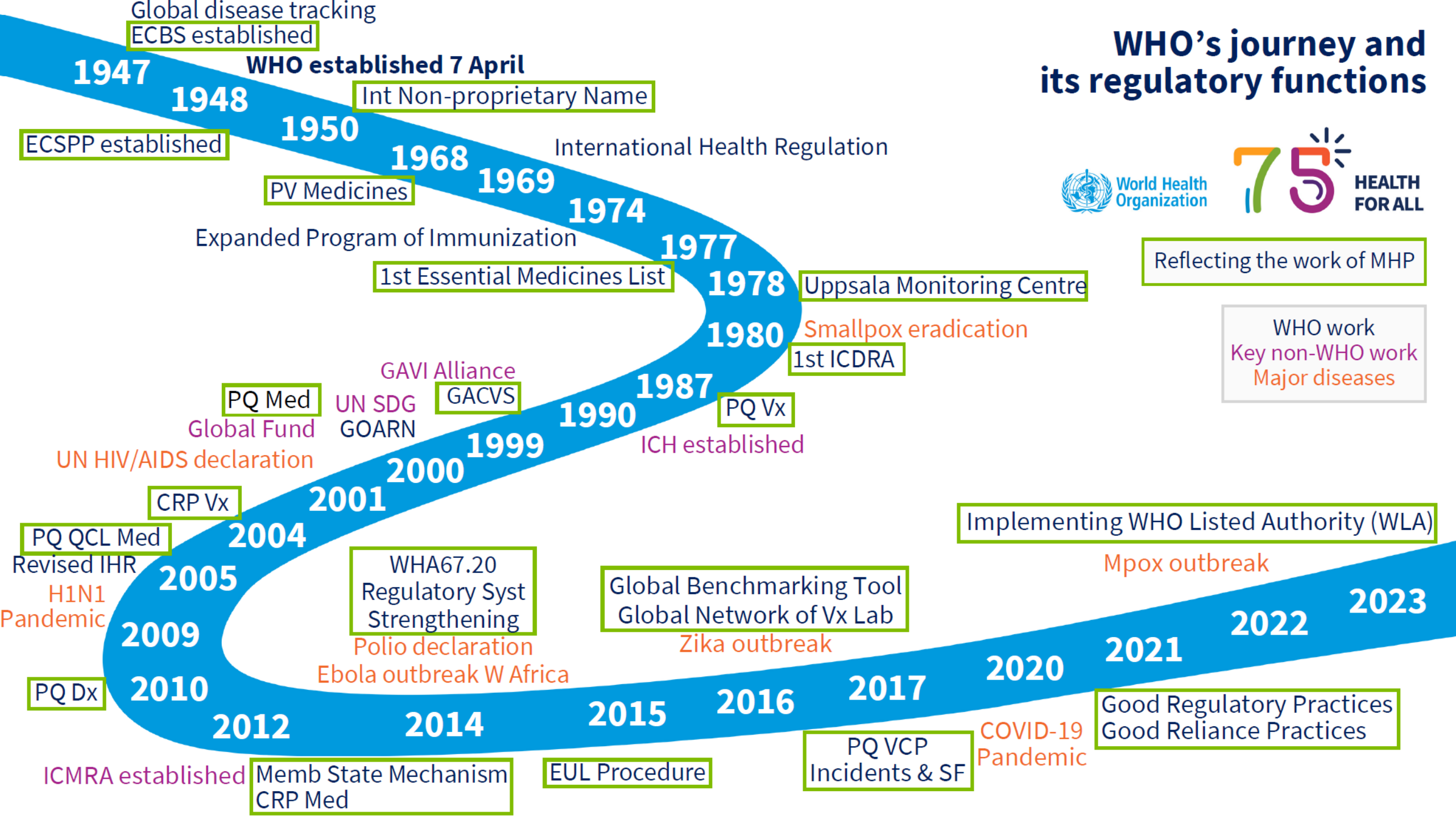
The pandemic as a catalyst for innovation:

A fit for purpose regulatory and ethics framework

Dr. Rogerio Gaspar
Director, Regulation and Prequalification
Access to Medicines and Health Products Division
World Health Organization

24 October 2023

WHO's journey and its regulatory functions



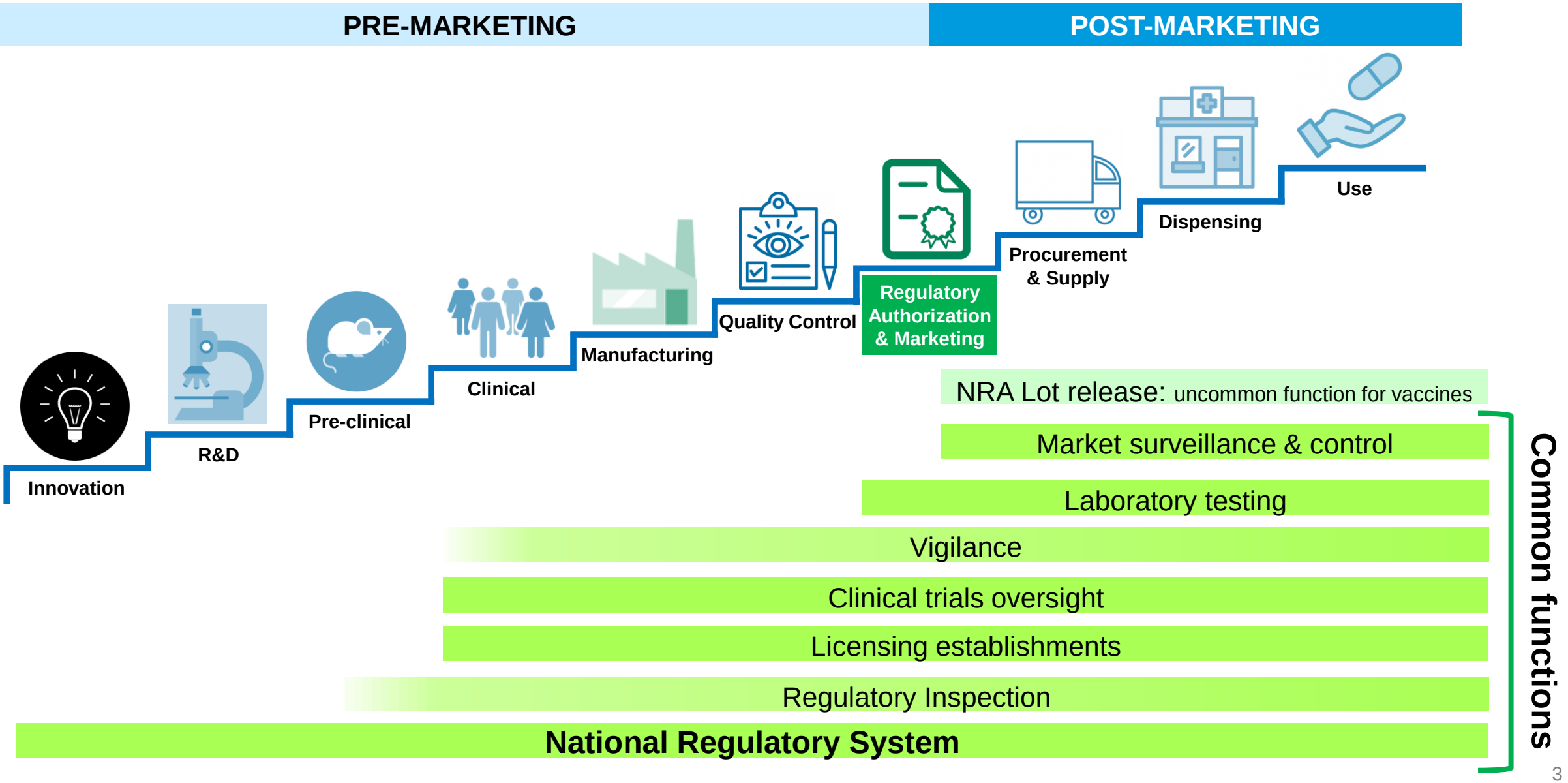
World Health Organization

75 HEALTH FOR ALL

Reflecting the work of MHP

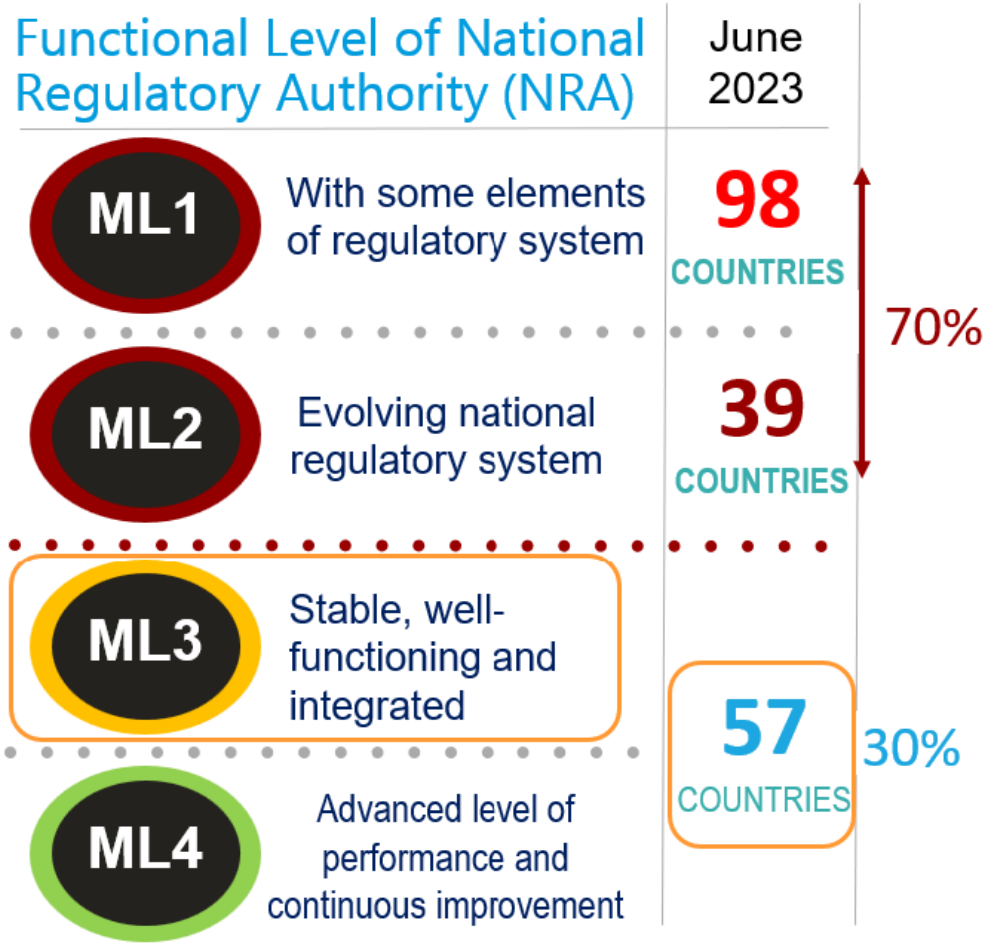
WHO work
Key non-WHO work
Major diseases

Regulatory functions in end-to-end product life-cycle:



Role of regulatory agency:

Responsible for ensuring quality, safety and efficacy / accuracy of health products throughout their life cycle



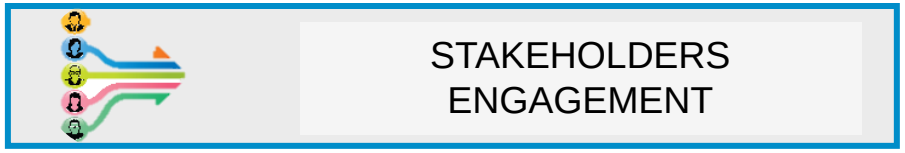
Functional regulatory agencies:

- Serve as fundamental basis for Universal health coverage
- Protect from health emergencies
- Contribute to healthier lives
- Power innovation, delivery & partnerships
- Deliver economic and social impact in countries

However, as **70% of NRAs** have inadequate functional systems, shared responsibilities for an end-to-end health product management are keys to assist these NRAs

List of NRAs operating at ML3 and ML4 as benchmarked against WHO GBT, 19 Oct 2023
List in alphabetical order

Reliance and Trust: the key to sharing responsibilities for an end-to-end health product management



- International regulatory collaboration and partnership based on **reliance and trust** is the only mechanism so far to ensure global safety, efficacy, and quality of medical products
- The **science and reliance-based regulatory pathways require joint forces** among WHO, NRAs, industry, procurers and other partners, ultimately ensuring delivery of quality assured medical products to everyone
- **Collaboration, partnership, harmonization and reliance embrace** equitable and timely access to quality-assured medical products, **strengthen global health resilience**, accelerate emergency preparedness, contribute to efficient use of time, human and financial resources, and improve the lives of people around the world
- WHO Listed Authorities (WLA) aims to build fundamental basis for trusted regulatory network

MHP special program (1):

WHO COVID-19 Technology Access Pool (C-TAP)

Established in May 2021

- A global one-stop shop for developers of:
  Diagnostics, Medical Devices, Therapeutics, Software/tools, Vaccines
- Flexible mechanism to negotiate licenses and tech transfer agreements with the support of implementing partners

Intellectual Property

Knowledge

Clinical Data

Technology holders

Support to:
Conduct technical assessment (suitability) Secure voluntary licensing / sub-licensing

Post-licensing recipient manufactures

Assists:
Knowledge transfer, Production scale-up
Regulatory, Market sharping & procurement

WHO Technology Access Pool Database

Provides access to dynamic info on selected COVID-19 health products

News release: 29 August 2023
New licensing agreements on COVID-19 technologies

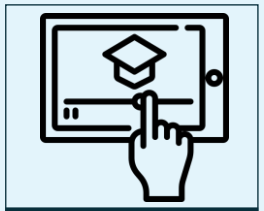
6

MHP special program (2):

WHO Biomanufacturing Training Initiative

To provide wide spectrum of technical and hands-on training

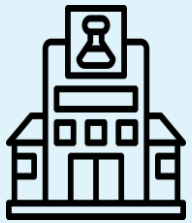
Ministry of Health and Welfare in Republic of Korea, a key partner with the **Global Training Hub for Biomanufacturing (GTH-B)**


Website, application

E-learning

GMP (Quality management, Hygiene, Qualification, Premises, Documentation, Preparing inspection),
GxP, Biosafety

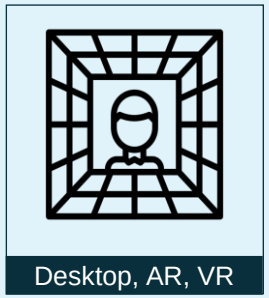
- Knowledge-based, Case studies
- Open-access


Factory school

Hands-on training in training facilities

Deep-dive process-oriented training (USP, DSP, F&F, QC)

- Portfolio of hands-on training in training institutions
- Training providers and Global training Hub in South Korea


Desktop, AR, VR

360 virtual training

Environment and aseptic behavior, process- oriented training (USP, DSP, F&F, QC)

- Virtual simulation in real production units
- Open-access
- Simulation exercises in a 360° environment of bioproduction with assessment

Global Bio Education Campus in Republic of Korea is expected to be launched end of 2024

News release: 26 May 2023
WHO and Republic of Korea sign landmark agreement to boost biomanufacturing capacity

7

MHP special program (3):

WHO mRNA Tech Transfer Hub Programme

Established in June 2021 with South Africa

Aims to enabling equitable access to mRNA vaccines by:

- Increasing the distribution of sustainable manufacturing capacity across countries
- Enhancing regional and inter-regional collaborations
- Developing and empowering the local workforce through tailored and inclusive training and expert support

Objectives:

1) establish and validate the mRNA tech platform (using COVID-19 vaccine as proof of concept)
2) transfer the technology to partners in LMICs
3) improve the technology and expand product pipelines

Progress so far:

- Technology developed at R&D scale
- Priority pathogens for R&D identified
- Engagement with partner MS to ensure strategy and implementation plans for sustainable mRNA technology
- Gaps/needs assessment of partners initiated in Q3 2023

Partners & government supporting hub

News release: 20 April 2023
[mRNA Technology Transfer Programme moves to the next phase of its development]

Thank you for your attention

Dr. Rogerio Gaspar
Director, Dept. Regulation and Prequalification (RPQ)
Div. Access to Medicines and Health Products, WHO

Subscribe to
WHO RPQ NEWSLETTER

Regulation and Prequalification

Access to Medicines and Health Products (MHP)

Assistant Director General

Yukiko Nakatani

Office of the ADG

MHP Special Programs

C-TAP

mRNA Tech Transfer Program

Gilles Forte

Health Products Policy and Standard (HPS)

Clive Ondari

Office of the Director

Sp Assist in Procurement & Supply chain principles

Technical Stand & Specifications

Office of the Unit Head

Norms & Stand for Biological products

Norms & Stand for Pharmaceuticals

Blood & other products of human origin

Medicines selection, IP & Affordability

Office of the Unit Head

Essential Medicines

Pricing & Affordability

IP Management

INN & classification of medical products

Office of the Unit Head

Exp Com on Drug Dependence

Office of the Unit Head

Access to Assistive Tech & Med Devices

Office of the Unit Head

Assistive Technology

Medical Devices & Diagnostics

Regulation and Prequalification (RPQ)

Rogério Gaspar

Knowledge Management Advisor

Quality Management System Advisor

Office of the Director

Prequalification

Deus Mubangizi

Office of the Unit Head

Inspection Services

IVD Assessment

Medicines Assessment

Vaccines & Immunization Devices Assessment

Vector Control Products Assessment

Medical Devices

Regulation and Safety

Hiiti Sillo

Office of the Unit Head

Regulatory Systems Strengthening

Regulatory Convergence and Networks

Facilitated Product Introduction

Laboratory Network and Services

Pharmacovigilance

Incidents and Substandard / Falsified Medical Products

Local Prod. & Assist.

Jicui Dong

Office of the Unit Head

Aug. 2023