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

**PRE-MARKETING**
- Innovation
- R&D
- Pre-clinical
- Clinical
- Manufacturing
- Quality Control

**POST-MARKETING**
- Procurement & Supply
- Dispensing
- Use
- NRA Lot release: uncommon function for vaccines
- Market surveillance & control
- Laboratory testing
- Vigilance
- Clinical trials oversight
- Licensing establishments
- Regulatory Inspection

**Common functions**

**National Regulatory System**
Role of regulatory agency:

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

### Functional Level of National Regulatory Authority (NRA)

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
<th>June 2023</th>
</tr>
</thead>
<tbody>
<tr>
<td>ML1</td>
<td>With some elements of regulatory system</td>
<td>98 COUNTRIES</td>
</tr>
<tr>
<td>ML2</td>
<td>Evolving national regulatory system</td>
<td>39 COUNTRIES</td>
</tr>
<tr>
<td>ML3</td>
<td>Stable, well-functioning and integrated</td>
<td>57 COUNTRIES</td>
</tr>
<tr>
<td>ML4</td>
<td>Advanced level of performance and continuous improvement</td>
<td></td>
</tr>
</tbody>
</table>

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

### 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

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

**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 sharpening & 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](#)
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)

E-learning
GMP (Quality management, Hygiene, Qualification, Premises, Documentation, Preparing inspection), GxP, Biosafety
- Knowledge-based, Case studies
- Open-access

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

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
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

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