WHO Regulatory Systems Strengthening Program

WHO/HIS/EMP/RHT/RSS/CRS
Outline

Sustainable Development Goals

WHA Resolution for regulatory System Strengthening

WHO regulatory system capacity building model

WHO Global Benchmarking Tool

Minimum Required Regulatory Functions

Innovative Approaches Toward Regulatory System Strengthening

Challenges

Global overview
WHO National Regulatory Authorities Global Benchmarking Tool (GBT) and pathway for regulatory systems strengthening
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.
WHA Resolution 67.20
What WHO should do

To continue to support Member States upon their request in the area of regulatory system strengthening, including, as appropriate, by continuing to:

- **Evaluate**
  - Evaluate national regulatory systems

- **Tools**
  - Apply WHO evaluation tools

- **Performance**
  - Generate and analyze evidence of regulatory system performance

- **IDPs**
  - Facilitate the formulation and implementation of institutional development plans

- **Technical support**
  - Provide technical support to national regulatory authorities and governments
WHA Resolution 67.20
What WHO should do

- Norms and standards
- Capacity building in developing countries
- Networks
- Medical devices including Diagnostics
- ICDRA
- WHO PQ program
- Health system strengthening
- International and regional collaboration
- Regulation of complex biological
WHO capacity building model
WHO NRA 5 step capacity building

1. Development of NRA benchmarking tool
   - Revision of indicators & benchmarking process

2. Benchmarking of NRA
   - Re-benchmarking Based on a risk management approach

3. Formulation of Institutional Development Plan (IDP)
   - With or without a road map for prequalification of products

4. Providing technical support, Training/Learning, networking,
   - WHO support through: Global Learning Opportunities (GLO)
     Technical Support In-country training Networking Harmonization

5. Monitoring progress and impact
   - WHO electronic platform to monitor NRAs information and benchmarking, IDP, training, etc.

Minimal capacity met Vaccine: eligibility for PQ
WHO NRA Benchmarking Policy

Benchmarking Methodology

Rapid Benchmarking

Pre visit

Self benchmarking

Benchmarking Follow up and Monitoring

Validation of information

Pre IDP

Observed Audit

IDP implementation (Monitoring + Capacity building activities)

Vigilance field visit
WHO Global Benchmarking Tool
Structure/Hierarchy

National Regulatory System (NRS) and Functions (NRF)

1. Regulatory System + Common Function
2. Non Common Functions

<table>
<thead>
<tr>
<th>Common Function</th>
<th>Non Common Functions</th>
</tr>
</thead>
<tbody>
<tr>
<td>01-NATIONAL REGULATORY SYSTEM</td>
<td>09-NRA LOT RELEASE</td>
</tr>
<tr>
<td>02-REGISTRATION AND MARKETING AUTHORIZATION</td>
<td></td>
</tr>
<tr>
<td>03-VIGILANCE</td>
<td></td>
</tr>
<tr>
<td>04-MARKET SURVEILLANCE AND CONTROL</td>
<td></td>
</tr>
<tr>
<td>05-LICENSE PREMISES</td>
<td></td>
</tr>
<tr>
<td>06-REGULATORY INSPECTION</td>
<td></td>
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<tr>
<td>07-LABORATORY ACCESS AND TESTING</td>
<td></td>
</tr>
<tr>
<td>08-CLINICAL TRIAL’S OVERSIGHT</td>
<td></td>
</tr>
</tbody>
</table>
WHO Global Benchmarking Tool
Structure/Hierarchy

Indicators Categorization (cross cutting subjects)

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

Categories enable assessment of cross sectional subjects (across some and/or all functions)
WHO GBT Performance Maturity Levels

1. No formal approach
   - Some elements of regulatory system exist
   - Can be considered as functional if rely on other regulators for some specific functions

2. Reactive approach
   - Evolving national regulatory system that partially performs essential regulatory functions

3. Stable formal system approach
   - Stable, well-functioning and integrated regulatory system
   - Target of WHA Resolution 67.20

4. Continual improvement emphasized
   - Regulatory system operating at advanced level of performance and continuous improvement
   - Advanced/reference Regulatory Authorities

ISO 9004
Model for adoption of Maturity Level Concept Maturity Level Spider Web

• By adoption of the maturity level concept, gaps are easily figured out (inter-and-intra regulatory functions) and hence capacity building priorities are defined as shown in this example!

• In addition, maturity level adoption enable customization of the tool for benchmarking of NRAs of varying capacities.
Minimum Required Regulatory Functions
# Proposed core regulatory functions and minimum maturity level required according to the source of products

**MINIMUM CAPACITY**

<table>
<thead>
<tr>
<th>Core Functions &amp; Maturity level required to meet minimum capacity</th>
<th>Producing countries</th>
<th>Non producing countries</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Vaccine (PQ)</td>
<td>Vaccine (NPQ)</td>
</tr>
<tr>
<td>National Regulatory System (RS)</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Registration and Marketing Authorization (MA)</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Vigilance (VL)</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Market Surveillance and Control (MC)</td>
<td>3</td>
<td>NA</td>
</tr>
<tr>
<td>Licensing Premises (LI)</td>
<td>3</td>
<td>2&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Regulatory Inspection (RI)</td>
<td>3</td>
<td>2&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Laboratory Access and Testing (LA)</td>
<td>3</td>
<td>NA</td>
</tr>
<tr>
<td>Clinical Trials Oversight (CT)</td>
<td>3</td>
<td>2&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>National Lot Release (LR)</td>
<td>3&lt;sup&gt;d&lt;/sup&gt;</td>
<td>NA</td>
</tr>
</tbody>
</table>

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a) Thru reliance/recognition  
b) apply for GDP and may be GCP  
c) applies in case of CT performed in-country  
d) applies only for vaccines and blood products  

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10/10/2017 | WHO National Regulatory Authorities Global Benchmarking Tool (GBT) and pathway for regulatory systems strengthening
The Future: new business model and innovative approaches

Development of NRA benchmarking tool

Benchmarking of NRA

Formulation of Institutional Development Plan (IDP)

Providing technical support, Training/Learning, networking,

Monitoring progress and impact

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1. Revision of indicators & benchmarking process
2. Re-benchmarking Based on a risk management approach
3. With or without a roadmap for prequalification of products
4. WHO support through: Global Learning Opportunities (GLO), Technical Support In-country training Networking Harmonization
5. WHO electronic platform to monitor NRAs information and benchmarking, IDP, training, etc.

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Minimal capacity met
Vaccine: eligibility for PQ

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CoRTE
CIP
Challenges
**Identified challenges**

- Absence of national policy and strategic objectives for establishing and/or developing further a National Regulatory Authority (NRA)

- Lack of minimum resources to establish and sustain regulatory oversight

- Unclear vision and mission (what should be done and what should not)
  - Avoiding duplication, reliance and recognition
  - Regulatory activities that could be done collectively by countries

- Access vs. quality

- Long term process, required continues commitment and engagement
WHO NRA Assessment Visits: 2014

NRA assessment visits

- NRA assessment conducted
- NRA assessment not conducted

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area of its authorities, or concerning the delimitation of its frontiers or boundaries.

Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.


Map Production: Public Health Information and Geographic Information Systems (GIS)

World Health Organization in collaboration with P&B CONSULTING
Countries targeted for WHO Regulatory System Strengthening Program 2016-2017:

**Formal Benchmarking**
- India
- Papua new guinea
- Timor-Leste
- Tanzania
- Burundi
- Mozambique
- Ethiopia
- Kenya
- Djibouti
- Eritrea
- Sudan
- South Sudan
- Somalia
- Uganda
- Serbia

**Self Benchmarking**
- Afghanistan
- Pakistan
- Vietnam
- Malaysia
- Japan
- Iraq
- Jordan
- Lao's PDR
- Lebanon
- Mongolia
- Kyrgyzstan
- Syria
- Korea
- Bangladesh
- Cambodia
- Iran
- Iraq
- Gambia

(Updated 25 September 2017)

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STRENGTHENING NATIONAL REGULATORY AUTHORITIES (NRA) TRAINING CONDUCTED, 1996-2017
7562 PARTICIPANTS FROM NRAs, NCLs*, EPI** AND/OR VM

7562 head counts have been trained by WHO between 1996 till Sept. 2017

WHO/EMP/RHT/RSS/ NRA assessment group
### Status of National Regulatory Authority functions in the area of vaccine regulation, 2016.

As of Dec 2016, Source WHO/HQ/RSS/CRS

<table>
<thead>
<tr>
<th>Main source of vaccines</th>
<th>Functional (Number/%)</th>
<th>Not functional (Number/%)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Producing</td>
<td>36 (83%)</td>
<td>7 (17%)</td>
<td>43</td>
</tr>
<tr>
<td>2. Procuring</td>
<td>20 (41%)</td>
<td>28 (59%)</td>
<td>48</td>
</tr>
<tr>
<td>3. UN agency</td>
<td>10 (10%)</td>
<td>93 (90%)</td>
<td>103</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>66 (34%)</strong></td>
<td><strong>129 (66%)</strong></td>
<td><strong>194</strong></td>
</tr>
</tbody>
</table>
Thank you