WHO Regulatory Systems Strengthening Programme

WHO Global Benchmarking Tool
Overall regulatory systems’ maturity level of WHO Member States

- **ML 1**: 100 countries, 51%
- **ML 2**: 44 countries, 23%
- **ML 3 and 4**: 50 countries, 26%

(Updated 8 Feb 2019)
WHO MVP/RSS/CRS
To continue to support Member States upon their request in the area of regulatory system strengthening, including, as appropriate, by continuing to:

- Evaluate national regulatory systems
- Apply WHO evaluation tools
- Generate and analyze evidence of regulatory system performance
- Facilitate the formulation and implementation of institutional development plans
- 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 NRA 5 step capacity building

1. Development of NRA benchmarking tool
2. Benchmarking of NRA
3. Formulation of Institutional Development Plan (IDP)
4. Providing technical support, Training/Learning, networking,
5. Monitoring progress and impact

Minimal capacity met
Eligibility for vaccine PQ
WHO listed NRAs
Global context: different assessment tools collecting information from Regulatory Authorities and affiliated institutions
Strategic direction
Development of the WHO Global Benchmarking Tool (GBT)

Unification of WHO tools + Convergence with non WHO tools = WHO Global Benchmarking Tool
Development of the Global Tool (2/4)

- WHO-PAHO meeting
- Revision V
- WHO-PAHO meeting
- BRN-TSN-RSS workshop for integration of blood products into GBT
- ECBS and BRN
- WHO-PAHO F-to-F meeting

Timeline:
- May
- Aug
- Nov
- Feb
- June
- Aug
- Sep
- Oct

2016

2017

Continue on next page
Development of the Global Tool (3/4)

- **WHO-PAHO meeting**
  - Update TOR for WGs

- WGs experts share written responses

- WGs WebEx discussions

- Consolidate experts comments

- Field testing of revision VI

- Reflection of agreed amendments

- WGs F2F meeting

- Compile comments

- Publish on the WHO website for public consultation

**Timeline:**
- **Jan-Feb**
- **Apr**
- **May**
- **Jun**
- **Jul**

**Dates:**
- 8-10
- 11
- 25
- 1
- 8
- 6
- 9
- 23-25

**2018**
Development of the Global Tool (4/4)

- WGs F2F meeting
- Publish summary of comments and responses
- Edit the GBT draft revision VI
- Pilot the GBT draft revision VI
- Final adjustment, editing and publication of GBT revision VI
- Translate and publish GBT revision VI in Spanish and French
- Phasing in of GBT revision VI

Timeline:
- Jul
- Aug
- Sep
- Oct
- Nov
- Q1

2018
2019
Access to Safe, Effective, Quality and Affordable Medical Products

Legal framework mandate and enforcement power

Norms and standards

Leadership, coordination & Strategic Planning

Quality Management /Risk Management System

Resources HR, FR, IMS, Infrastructure

Inspection and Audit

Vigilance and Surveillance

Quality control/testing

Scientific evaluation and oversight

Assuring quality of products

Good Regulatory Practices (GRP)
WHO RECOMMENDED REGULATORY FUNCTIONS FOR MEDICINES, VACCINES BASED ON PRODUCT LIFECYCLE
WHO Global Benchmarking Tool

Structure/Hierarchy

- System Function
- Indicators
- Sub-Indicators
- Questionnaire for Other Products/Activities
- The Fact Sheet
WHO Global Benchmarking Tool
Structure/Hierarchy

Indicators Categorization (cross cutting subjects)

- Legal provisions, regulations and guidelines
- Organization and governance
- Policy and strategic planning
- Leadership and crisis management
- Transparency, accountability and communication
- Quality and risk management system
- Regulatory process
- Resources (HR, FR, Experts, Infrastructure, Equipment and IMS)
- Monitoring progress and assessing impact
WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems

Regulatory systems play a key role in assuring the quality, safety, and efficacy of medical products. Effective regulatory systems are an essential component of health systems and contribute to desired public health outcomes and innovation.

The Global Benchmarking Tool (GBT) represents the primary means by which the WHO objectively evaluates regulatory systems, as mandated by WHA Resolution 67.20 on Regulatory System Strengthening for medical products. The tool and benchmarking methodology enables the WHO and regulatory authorities to:

- identifies strengths and areas for improvement;
- facilitate the formulation of an institutional development plan (IDP) to build upon strengths and address the identified gaps;
- prioritize IDP interventions; and
- monitor progress and achievements.

The World Health Organization (WHO) began assessing regulatory systems in 1997 using a set of indicators designed to evaluate the regulatory programme for vaccines. Since that time, a number of tools and revisions were introduced. In 2014 work began on the development of a unified tool for evaluation medicines and vaccines regulatory programmes following a mapping of existing tools in use within and external to WHO.

The development of the current GBT Revision VI takes into consideration input received from two international consultations with Member States in 2015, a public consultation in early 2018 and a series of meetings involving experts from regulatory authorities from different parts of the world.

The GBT Revision VI replaces all tools previously used by WHO, representing the first truly ‘global’ tool for benchmarking regulatory systems. The GBT is designed to evaluate the overarching regulatory framework and the component regulatory functions (e.g. clinical trial oversight) through a series of sub-indicators that may also be grouped and examined according to nine cross-cutting categories or themes, for example, quality and risk management system. Fact sheets have been developed for
Current Status of Regulatory Systems
WHO Global Benchmarking (for medicines and vaccines: as of September 2019)

<table>
<thead>
<tr>
<th>ISO 9004</th>
<th>WHO GBT</th>
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<tbody>
<tr>
<td><strong>1</strong> No formal approach</td>
<td>Can ensure the quality of products if rely on ML3 / ML4 regulatory systems</td>
</tr>
<tr>
<td><strong>2</strong> Reactive approach</td>
<td>Evolving national regulatory system that partially performs essential regulatory functions</td>
</tr>
<tr>
<td><strong>3</strong> Stable formal system approach</td>
<td>Stable, well-functioning and integrated regulatory system</td>
</tr>
<tr>
<td><strong>4</strong> Continual improvement emphasized</td>
<td>Regulatory system operating at advanced level of performance and continuous improvement</td>
</tr>
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</table>

- **100 COUNTRIES**
- **44 COUNTRIES**
- **50 COUNTRIES**
### Updated Figures of the WHO GBT revision VI

<table>
<thead>
<tr>
<th>Item</th>
<th>Function</th>
<th>RS</th>
<th>MA</th>
<th>VL</th>
<th>MC</th>
<th>LI</th>
<th>RI</th>
<th>LA</th>
<th>CT</th>
<th>LR</th>
<th>Grand Total</th>
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<tr>
<td><strong>Number of Sub-Indicators</strong></td>
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<td>60</td>
<td>35</td>
<td>26</td>
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<td>19</td>
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<td>Sub-Indicators measuring maturity level 1</td>
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<td>6</td>
<td>5</td>
<td>3</td>
<td>2</td>
<td>3</td>
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<td>1</td>
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<tr>
<td></td>
<td>Sub-Indicators measuring maturity level 2</td>
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<td>3</td>
<td>4</td>
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<td></td>
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<td>3</td>
<td>8</td>
<td>6</td>
<td>3</td>
<td>2</td>
<td><strong>56</strong></td>
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</table>

**Minimal capacity**

**Advanced/reference NRAs**
• Comprehensive system-based benchmarking
• Integration of different medical product streams
• Enhanced ability for customization of the tool
• Adoption of maturity concept based on ISO standard
• Integration of SF related indicators
• Expanded benchmarking of QMS for NRAs
• Categorization of the indicators enabling transverse benchmarking
• Link with predecessor tools
• Updating and expansion of regulatory guidelines
• Comprehensive guidance for benchmarking
• Maintenance of functionality concept as part of eligibility criteria for WHO prequalification
computerized Global Benchmarking Tool (cGBT)

<table>
<thead>
<tr>
<th>Country</th>
<th>Scope</th>
<th>Date of visit</th>
<th>Type of visit</th>
<th>Status</th>
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<tbody>
<tr>
<td>RS</td>
<td>All</td>
<td>1 - 31 Jul 2019</td>
<td>Benchmarking</td>
<td>Draft</td>
</tr>
<tr>
<td>MA</td>
<td>All</td>
<td>1 - 31 Jul 2019</td>
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<td>Draft</td>
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<tr>
<td>VL</td>
<td>All</td>
<td>1 - 31 Jul 2019</td>
<td>Benchmarking</td>
<td>Draft</td>
</tr>
<tr>
<td>MC</td>
<td>All</td>
<td>1 - 31 Jul 2019</td>
<td>Benchmarking</td>
<td>Draft</td>
</tr>
<tr>
<td>LI</td>
<td>All</td>
<td>1 - 31 Jul 2019</td>
<td>Benchmarking</td>
<td>Draft</td>
</tr>
<tr>
<td>RI</td>
<td>All</td>
<td>1 - 31 Jul 2019</td>
<td>Benchmarking</td>
<td>Draft</td>
</tr>
<tr>
<td>LT</td>
<td>All</td>
<td>1 - 31 Jul 2019</td>
<td>Benchmarking</td>
<td>Draft</td>
</tr>
<tr>
<td>CT</td>
<td>All</td>
<td>1 - 31 Jul 2019</td>
<td>Benchmarking</td>
<td>Draft</td>
</tr>
<tr>
<td>LR</td>
<td>All</td>
<td>1 - 31 Jul 2019</td>
<td>Benchmarking</td>
<td>Draft</td>
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</table>
### Recommended activities to be included in Institutional Development (IDP)

<table>
<thead>
<tr>
<th>Regulatory functions</th>
<th>Total number of Recommendations</th>
<th>No. of recommendations required to reach ML3</th>
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</thead>
<tbody>
<tr>
<td>01-NATIONAL REGULATORY SYSTEM (RS)</td>
<td>29</td>
<td>10</td>
</tr>
<tr>
<td>02-REGISTRATION AND MARKETING AUTHORIZATION (MA)</td>
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<td>12</td>
</tr>
<tr>
<td>03-VIGILANCE (VG)</td>
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<td>9</td>
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<tr>
<td>04-MARKET SURVEILLANCE AND CONTROL (MC)</td>
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</tr>
<tr>
<td>05-LICENSING PREMISES (LI)</td>
<td>5</td>
<td>1</td>
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<tr>
<td>06-REGULATORY INSPECTION (RI)</td>
<td>13</td>
<td>4</td>
</tr>
<tr>
<td>07-LABORATORY ACCESS AND TESTING (LA)</td>
<td>3</td>
<td>1</td>
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<tr>
<td>08-CLINICAL TRIAL’S OVERSIGHT (CT)</td>
<td>15</td>
<td>10</td>
</tr>
<tr>
<td>09-NRA LOT RELEASE (LR)</td>
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<td>2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>123</strong></td>
<td><strong>50</strong></td>
</tr>
</tbody>
</table>
China: The Success Story

NRA Benchmarking

1st PQ vaccine

More vaccine submitted for PQ

Functional NRA, after benchmarking in Dec 2010

IDP

NRA Re-Assessment

2005

Mar/2011

Oct/2013

Q2/2014

Newly accessible Japanese encephalitis vaccine will make saving children easier in developing countries

First vaccine from China to be prequalified by WHO

9 OCTOBER 2013 | GENEVA - A newly accessible vaccine against Japanese encephalitis is going to make the protection of more children in developing countries easier. The vaccine, manufactured in China, only needs to be given in one dose, it can be used for infants, and it is less expensive than other Japanese encephalitis vaccines.
Tanzania: The Success Story

Tanzania is first African country to reach an important milestone in the regulation of medicines

Roadmap for WHO regulatory strengthening program
Tanzania Food and Drugs Authority (TFDA)

<table>
<thead>
<tr>
<th>NRA Function assessed</th>
<th>Sub Indicators %</th>
<th>Sub Indicators %</th>
<th>Maturity level</th>
<th>Maturity level</th>
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</thead>
<tbody>
<tr>
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<td>94%</td>
<td>95%</td>
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<tr>
<td>02-REGISTRATION AND MARKETING AUTHORIZATION (RMA)</td>
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<td>98%</td>
<td>2</td>
<td>3</td>
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<tr>
<td>03-VIGILANCE (PVU)</td>
<td>81%</td>
<td>94%</td>
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<td>3</td>
</tr>
<tr>
<td>04-MARKET SURVEILLANCE AND CONTROL (MSC)</td>
<td>90%</td>
<td>90%</td>
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<td>3</td>
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<tr>
<td>05-LICENSING PREMISES (LIC)</td>
<td>83%</td>
<td>88%</td>
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<td>3</td>
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<tr>
<td>06-REGULATORY INSPECTION (RI)</td>
<td>83%</td>
<td>91%</td>
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<tr>
<td>07-LABORATORY ACCESS AND TESTING (LAT)</td>
<td>97%</td>
<td>100%</td>
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<td>08-CLINICAL TRIAL'S OVERSIGHT (CTO)</td>
<td>98%</td>
<td>98%</td>
<td>3</td>
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</tbody>
</table>
WHO RECOMMENDED REGULATORY FUNCTIONS FOR MEDICINES, VACCINES AND BLOOD PRODUCTS BASED ON PRODUCT LIFECYCLE

Pre-clinical

Clinical

Production & Quality Control

Marketing and sales

Post-Marketing

Common Regulatory Functions for medicines & vaccines and blood products

National Regulatory System (RS)

Regulatory Inspection (RI)

Laboratory access and Testing (LA)

Clinical Trial’s Oversight (CT)

Vigilance (PV)

Licensing premises (LI)

Registration & marketing authorization (MA)

Market surveillance and Control (MS)

NRA Lot release (LR)

Approval of blood and blood components (product and/or process approval)

Regulatory oversight of associated substances and medical devices including IVD

Next steps: Medical devices

Non Common Regulatory Function for vaccines and blood products

Non Common Regulatory Functions for blood products
Countries benchmarked against GBT
Jan 2016 - Sep 2019

**Formal Benchmarking**
- India
- Papua new guinea
- Timor-Leste
- Tanzania
- Burundi
- Ethiopia
- Mozambique
- Kenya
- Djibouti
- Eritrea
- Sudan
- South Sudan
- Somalia
- Uganda
- Serbia
- Cambodia
- Lao PDR
- Thailand
- Indonesia
- Kazakhstan
- Vietnam
- Rwanda
- Ghana
- El Salvador
- Nigeria

**Self Benchmarking**
- Afghanistan
- Pakistan
- Malaysia
- Japan
- Iraq
- Jordan
- Lebanon
- Mongolia
- Kyrgyzstan
- Korea
- Bangladesh
- Iran
- Syria
- Egypt
- Saudi Arabia
- Gambia
- Benin
- Burkina Faso
- Guinea
- Sierra Leone
- Montenegro
- Bosnia and Herzegovina
- Macedonia
- Albania
- Kosovo area*


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 (WHO) concerning the legal status of any country, territory, city or area of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on map represent approximate border lines for which there may be not yet be full agreement.
Important Links

- Go to our Regulatory system strengthening website
- Go to the Global Benchmarking Tool
- Go to SharePoint site
- Go to GBT online training
Thank you

Dr Alireza Khadem
Email: khadembroojerdia@who.int

Regulatory Systems Strengthening (RSS)
Regulation of Medicines and Other Health Technologies (RHT)
World Health Organization (Geneva, Switzerland)