WHO Global Benchmarking Tool

Committee on Stronger Food and Drug Regulatory Systems Abroad
January 9 2019

Mike Ward
WHO Geneva
Regulatory System Strengthening Program

WHO began program of benchmarking and strengthening regulatory systems in 1997, beginning with vaccines programs.

Importance of strong, efficient regulatory systems recognized by WHA Resolution 67.20 – Regulatory System Strengthening for Medical Products.

Ultimate goal to promote access to quality assured medical products – SDG 3 target...access to safe, effective, quality and affordable essential medicines and vaccines for all.
Global Benchmarking Tool

The WHO Global Benchmarking Tool (GBT) provides an objective and well tested methodology for benchmarking regulatory systems, establishing an institutional development plan (IDP) for addressing areas for improvement and for monitoring progress.

GBT also allows for an assessment of the maturity of the regulatory system with the objective of bringing all regulatory authorities to a level commensurate with a stable, well-functioning system.
WHO NRA Assessment Visits: 1997

Assessment visit conducted
- NRA assessment conducted
- NRA assessment not conducted

World Health Organization

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 or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.


WHO 2008: All Rights Reserved.
WHO NRA Assessment Visits: 2015

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 or 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
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 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
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 Global Benchmarking Tool

Structure/Hierarchy

- SYSTEM FUNCTION
- INDICATORS
- SUB-INDICATORS
- QUESTIONNAIRE FOR OTHER PRODUCTS/ACTIVITIES
- THE FACT SHEET
WHO Global Benchmarking Tool

Structure/Hierarchy

National Regulatory System (NRS) and Functions (NRF)

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

Common Function
- 01-NATIONAL REGULATORY SYSTEM
- 02-REGISTRATION AND MARKETING AUTHORIZATION
- 03-VIGILANCE
- 04-MARKET SURVEILLANCE AND CONTROL
- 05-LICENSING PREMISES
- 06-REGULATORY INSPECTION
- 07-LABORATORY ACCESS AND TESTING
- 08-CLINICAL TRIAL’S OVERSIGHT

Non Common Functions
- 09-NRA LOT RELEASE

WHO/EMP/RHT/RSS/ NRA assessment group
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

Categories enable assessment of cross sectional subjects (across some and/or all functions)
WHO Global Benchmarking Tool

Structure/Hierarchy

Sub-Indicators Categorization

**Functionality**

1. Critical

**Maturity**

1. Addressing Maturity Level 1
2. Addressing Maturity Level 2
3. Addressing Maturity Level 3
4. Addressing Maturity Level 4

WHO-PAHO working group discussions for revision and finalization of the Global Benchmarking Tool (GBT)
WHO GBT Performance Maturity Levels

ISO 9004

1. No formal approach
   - Some elements of regulatory system exist
   - Can be consider 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 regulators
Overall regulatory systems’ maturity level of WHO Member States

- ML 1: 99 Countries (51%)
- ML 2: 45 Countries (23%)
- ML 3 and 4: 50 Countries (26%)

(Updated 15 May 2018)
WHO MVP/RSS/CRS
WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems

The WHO Global Benchmarking Tool (GBT) is a means by which WHO evaluates regulatory systems through a comprehensive and systematic benchmarking. The tool and benchmarking methodology:

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

The development of the WHO Global Benchmarking Tool is the result of a collaborative effort between WHO headquarters and Regional Offices with support from country regulators. The tool builds on other WHO tools including the WHO Vaccine data collection tool, WHO Data Collection Tool for the Review of Drug Regulatory Systems and the WHO Regional Office for the Americas (PAHO/AMRO) assessment tools and includes features of proven benefit from those tools such as computerization, categorization of indicators/sub-indicators and inclusion of fact sheets.

New features include:

- incorporation of good regulatory practices (GRP) principles;
- adoption of the maturity level concept referenced in ISO 9004 standard;
- inclusion of a group of indicators to assess regulatory measures to prevent, detect, and respond to substandard and falsified (SF) medical products;
- integration of the regulatory relevant indicators from the WHG good governance for medicines (GGM) assessment; and
- expansion of the indicators for measurement of Quality Management Systems (QMS) of different regulatory functions.

Related links:
- National Regulatory Systems (RS) fact sheet
  - pdf, 1.40Mb
- Registration and Marketing Authorization (MA) fact sheet
  - pdf, 645kb
- Vigilance (VL) fact sheet
  - pdf, 645kb
- Market Surveillance and Control (MC) fact sheet
  - pdf, 633kb
- Licensing Establishments (LE) fact sheet
  - pdf, 490kb
- Regulatory Inspection (RI) fact sheet
  - pdf, 665kb
- Laboratory Testing (LT) fact sheet
  - pdf, 137kb
- Clinical Trials Oversight (CT) fact sheet
WHO Listed Authority (WLA)

Term ‘Stringent Regulatory Authority’, defined as original ICH member/observer, was developed to promote reliance and guide procurement decisions - widely used and recognized.

Concerns with term SRA; with the fact that ICH is a harmonization initiative for pharmaceuticals, not a body with a remit or competence to assess regulatory capacity; coupled with expanding membership.

WHO Expert Committee (Oct 2017) considered new WHO proposal and made a number of recommendations.
Expert Committee Recommendations

Term SRA be replaced by “WHO-Listed Authority” (WLA)
Currently identified “SRAs” will be regarded as WHO-Listed
Designation of additional NRAs be based on WHO
Global Benchmarking Tool (GBT) + completion of ‘confidence-building process’
Procedure for listing be developed through usual public consultation process
Establishing system for recognizing and listing WLA

Concept note under development that will

• present proposed definition for WLA
• define proposed criteria and process for designating an NRA as WLA
• describe the proposed process and timelines for finalizing process for designating a WLA

Given implications, WHO intends to undertake broader consultation process

Targeting early 2019 for adoption, together with introduction of WHO GBT (version VI)
Considerations

Voluntary process; outcome to be made public

Process must be transparent, practical, flexible and equitable

WLA will include both ML 3 and ML 4 agencies. Listing will specify

Process for renewal, including of former SRAs, will be developed taking into account existing evidence

Must ensure continued supply of quality assured products for use by UN procurement agencies/countries

WLA designation not intended to affect regional designations
Benefits

Provide a robust framework to promote trust, confidence and
too relyance and thereby enable efficient use of regulatory resources

Encourage continuous improvement of regulatory systems

Help guide procurement decisions on medical products by UN
and other agencies, as well as countries: global quality reference
for international and domestic supply, including for products not
eligible for PQ

Expand the pool of regulatory authorities contributing to
efficiency of Prequalification programme and the efficiency of the
PQ process and listing

Essentially means that marketing authorizations for WLAs would
be taken into account by PQT in a manner to be defined
**WLAs**

**ML 3 authority:**
- Target of WHA resolution 67.20: well-functioning system
- Equates with former ‘functional’ designation
- Remains prerequisite for vaccine manufacturer application to PQ
- Status could also be taken into account for medicines

**ML 4 authority:**
- Equates with SRA
- Could be for a specific program (generic medicines) or regulatory function (Inspection)
- Allows for abridged procedure, depending on scope of WHO evaluation
“The human being is the vital link in the chain of aircraft operations but is also by nature the most flexible and variable.”
Human resources constraints and financial constraints as one of the challenges for regulatory systems globally.
The need

Progress in harmonization, joint activities, and information and work-sharing,

• having an internationally accepted set of competences will maximize the benefits of collaboration and cooperation in medical product regulation.

WHO has established a well-recognized process for benchmarking and strengthening regulatory systems,

• the current approach in regulatory capacity development must include a common global competence framework if desired public health outcomes are to be achieved.
As part of regulatory systems strengthening, the WHO is working with partners to develop a global competency framework and global curricula to support training and professional development of regulatory staff.
Goal
A globally accepted competency framework that is adaptable is essential to ensure standardized training approach and systematic development of competent regulatory professionals.
Define occupational credential

A. Mandatory

Global Competency Model

B. Generic competencies (CORE)

Specific to the regulation of medical products

C. Occupation-related competencies

Foundation for success in the world of work
Stages of Professional Development / Skill Acquisition

The Global Competency Framework has three levels

- **Conscious incompetence**
  - Advanced beginner

- **Conscious competence**
  - Competent

- **Unconscious competence**
  - Proficient / Expert

RAPS: uses 4 professional levels for regulatory affairs professionals
EMA: uses 3-grade level for quality assessors
What’s next in 2019...

• Public consultation

• Piloting draft competence assessment tools in 2-3 countries

• Piloting in different settings
  • NRAs of different maturity levels
  • Regional settings
  • Training institutions

• Updating based on feedback from public consultation and pilot
Thank you for your attention
Back up slides
Robust assessment using relevant components of GBT and Confidence building exercise or ‘enhanced performance verification’ to confirm consistency in performance against international standards and best practices

Potential Elements of Confidence Building Framework

- Sampling of assessment reports
- Observed audits
- Time limited exchange of staff
- Participation in dossier reviews
- Laboratory proficiency testing
Attributes of a ML 4 Agency

Operates at an advanced level of performance and continuous improvement

Exercises good regulatory practices, strategic planning and effective risk-based and collaborative regulatory approaches that maximize use of available resources

Possesses necessary scientific capacity, resources, leadership and regulatory instruments to address complex and evolving regulatory issues and products