WHO benchmarking of regulatory systems – Updates and implications for Africa

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A Decade of regulatory harmonization in Africa: Where are we? Where do we go from here?
**WHA Resolution 67.20 in 2014**

✓ recognized the importance of strong regulatory systems to a well-functioning healthcare system and the attainment of health-related SDGs and UHC
 ✓ Basis for WHO RSS Programme

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**Objectives of WHO RSS Programme**

1. Evaluate national regulatory systems
2. Apply WHO evaluation tools
3. Generate and analyze evidence of regulatory system performance
4. Facilitate the formulation and implementation of institutional development plans
5. Provide technical support to national regulatory authorities and governments

**a. Build regulatory capacity in MS consistent with GRP**

b. Promote regulatory cooperation, convergence and transparency through networking, work-sharing and reliance
WHO Five-Step Capacity Building Model for National Regulatory Authorities (NRAs)
WHO benchmarking of regulatory systems

- WHO has been benchmarking regulatory systems since 1997
  - to identify gaps and improve capacity to regulate medical products
  - for vaccine manufacturers seeking WHO prequalification
    - an NRA must be ‘functional’ following WHO benchmarking

- 2016: a harmonized medicines & vaccines ‘Global Benchmarking Tool’ (GBT) and categorization of NRAs based on maturity levels instead of “functionality”

- A unified WHO GBT Revision VI published in December 2018
  - 268 Indicators measuring the maturity of a regulatory system and core regulatory functions
  - **GBT Plus** (+ blood and blood products would be published before end of 2019) & work started for medical devices & diagnostics
  - Available in English and French, translation to Spanish ongoing
  - Computerized GBT (cGBT) plus online training
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
Benchmarking Methodology

1. Pre visit
   - Pre IDP

2. Self benchmarking
   - Observed Audit
   - IDP implementation (Monitoring + Capacity building activities)
   - Vigilance field visit

3. Benchmarking
   - Validation of information

4. Follow up and Monitoring
   - Formal request from a MS
Maturity Levels of NRAs as defined by WHO GBT

1. **No formal approach**
   - Some elements of regulatory system exist
   - Can ensure the quality of products if rely on ML 3/ML 4 regulatory systems
   - 99 Countries

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

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

4. **Continual improvement emphasized**
   - Regulatory system operating at advanced level of performance and continuous improvement
   - Advanced and well resourced regulatory systems
   - 7 Countries
WHO Regulatory System Strengthening Programme

NRAs benchmarked against the WHO GBT between 2016 – 2019 (global)

**Benchmarking (rapid & formal)**
- 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.
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African NRAs benchmarked against WHO GBT between 2016 and 2019

**Formal Benchmarking**
- Tanzania
- Rwanda
- Nigeria
- Ghana

**Rapid Benchmarking**
- Burundi
- Mozambique
- Kenya
- Ethiopia
- Djibouti
- Eritrea
- Sudan
- South Sudan
- Somalia
- Uganda

**Self Benchmarking**
- Egypt
- Gambia
- Benin
- Burkina Faso
- Guinea
- Sierra Leone
- Cote d’Ivoire
- Senegal
- Togo
- Mali
- Guinea Bissau
- Liberia
- Niger
- Cape Verde
- Eswatini
- Botswana
- Angola
- Comoros
- Madagascar
- Malawi
- South Africa
- Lesotho
- Zambia
- Mauritius
- Congo DR
- Namibia
- Seychelles
- Zimbabwe

*Question: are RECs following implementation of recommendations?*  
(Updated Sep 2019)

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WHO works with Partners to address regulatory capacity gaps

- **System & Functions**
  - Regulator
  - Benchmarking (GBT)
  - Performance evaluation of regulators
  - Global competency framework (draft)

- **Training**
  - WHO guidelines related to regulatory functions (MA, RI, VL, QMS, LR, etc.)
  - Global and regional networks
  - GRP & GReIP guidelines
  - WHO Listed Authority (WLA)

- **Specialized technical support**
  - Variety of trainings for regulators in various areas including theoretical and hands on (incl. placements in mature NRAs)
  - Provide technical support to advise on regulatory matters

- **Developing regulatory guidelines**
- **Promoting harmonization**
- **Promoting reliance**

- **Benchmarking (Gap analysis)**

- **Capacity building**

- **Smart Regulation**
Lessons for Africa

• More countries going for formal benchmarking following completion of self-benchmarking
  ✓ 2 (2018) 3 (2019), 3 to 4 candidate countries expected in 2020
  ✓ Self-benchmarking workshop for OCEAC countries, Q1 2020

• A pool of assessors identified across the RECs, a resource for WHO and others

• Significant improvements in regulatory capacities e.g. Tanzania NRA achieving ML 3 in December 2018, more on the pipeline

• NRAs achieving ML 3 would be eligible for WHO Listed Authorities (WLA)
  ✓ Promotes trust, confidence and reliance
  ✓ Encourages continuous improvement

• Alignment of the GBT Indicators with AMRH M & E Framework

• However, some delays in completing self-benchmarking and implementation of IDPs
  ✓ Slow progress in enhancing regulatory capacities and regional collaboration
NRAs reaching ML 3 would be eligible for designation as WLAs following implementation of performance evaluation process – by product streams and regulatory functions.
Conclusions

- Strong regulatory system is an essential component of a well-functioning healthcare system - **critical path to innovation and access** to safe and quality assured medical products

  ✔ Significant role in achieving UHC and SDG 3 (target 3.8)

- WHO GBT truly a **global tool** to guide strategic investments in regulatory systems strengthening

  ✔ Promotes good regulatory practices, flexible regulatory frameworks, reliance and networking

- **Who will be reported as ML 3 during the 5th SCoMRA in 2021?**
Acknowledgement