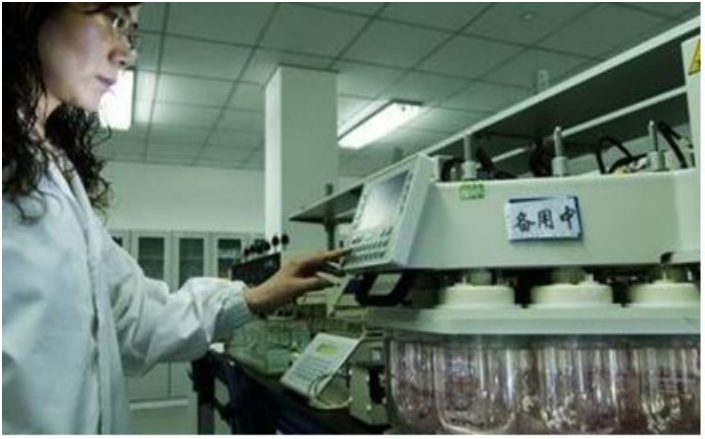


World Health Organization

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

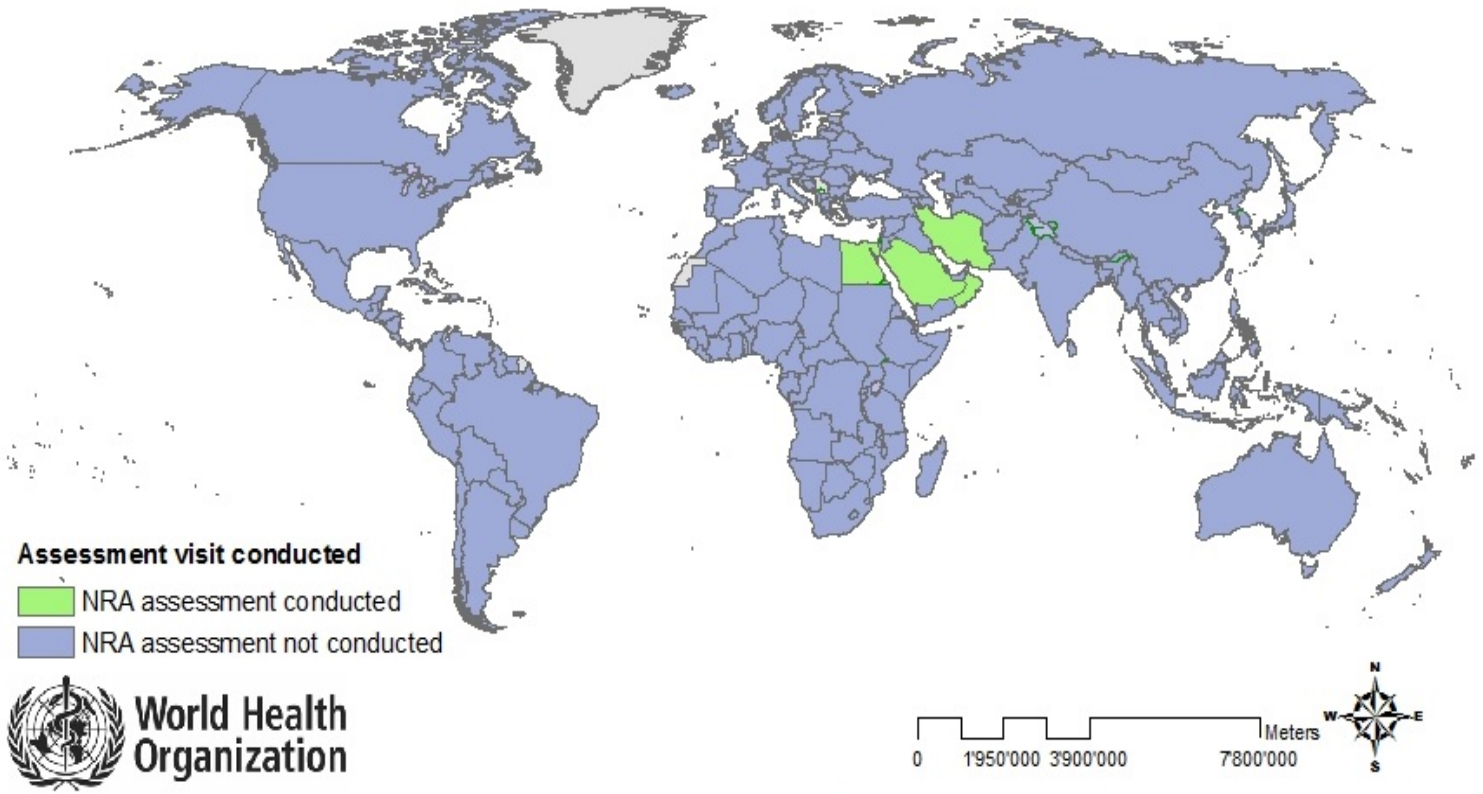
Ultimate goal to promote access to quality assured medical products – SDG 3 target…access to safe, effective, quality and affordable essential medicines and vaccines for all

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

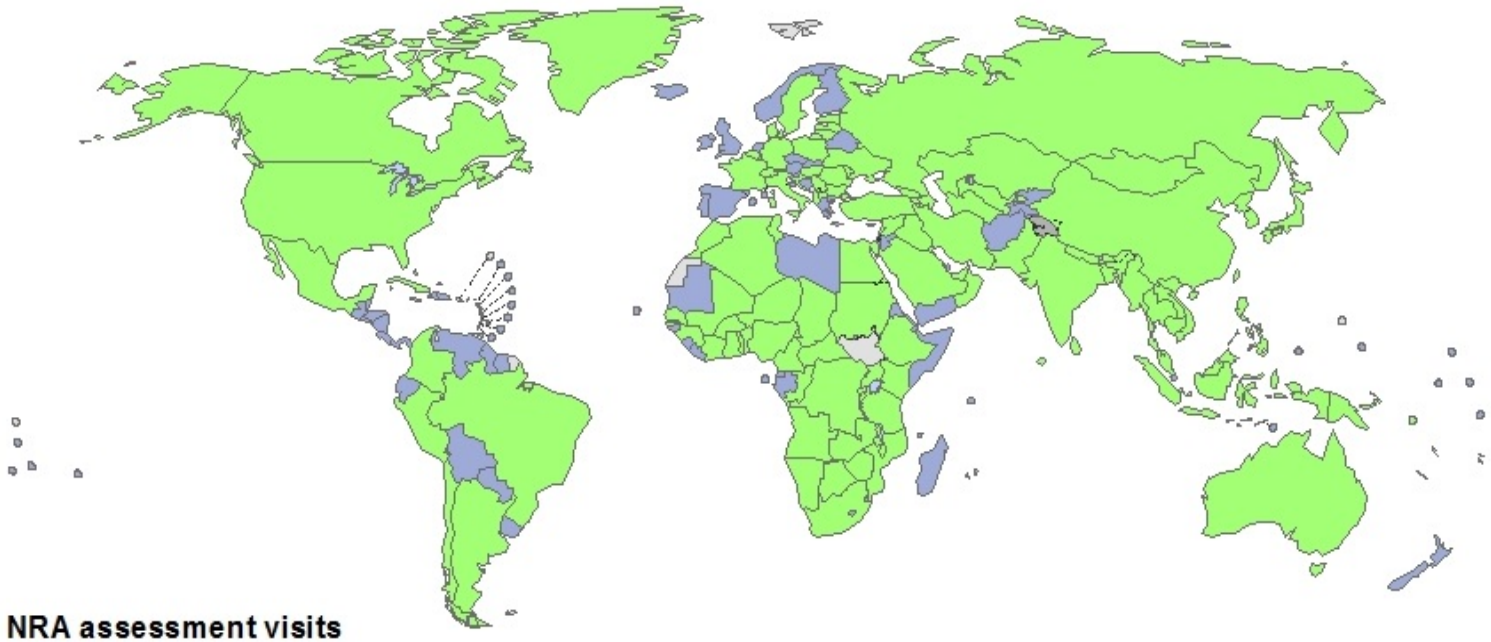
WHO NRA Assessment Visits: 1997



The boundaries and names shown and the designations used on this map do not only imply the expression of any opinion what sever 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 lines on maps represent approximate border lines for which there may not yet be full agreement.
Data Source: World Health Organization, Immunization Vaccines and Biologicals (IVB). Updated as of 2 May 2011
Map Production: Public Health Information and Geographic Information Systems (GIS) World Health Organization in collaboration with P&B Consulting

WHO NRA Assessment Visits: 2015

World Health Organization



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Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.
Data Source: World Health Organization, Immunization Vaccines and Biologicals (IVB). Updated as of 5 June 2013
Map Production: Public Health Information and Geographic Information Systems (GIS)
World Health Organization in collaboration with P&B CONSULTING

World Health Organization

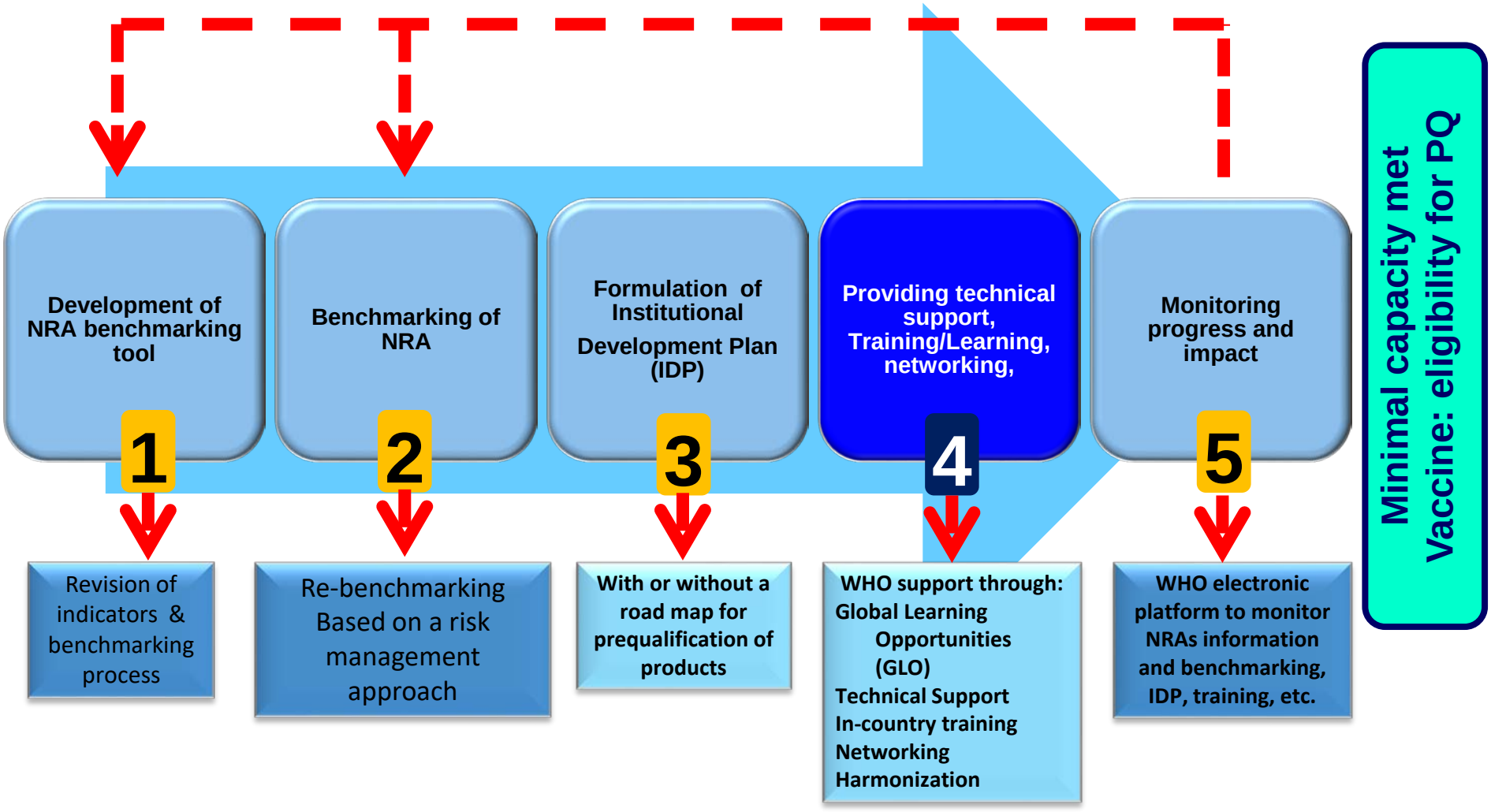
WHA Resolution 67.20

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:

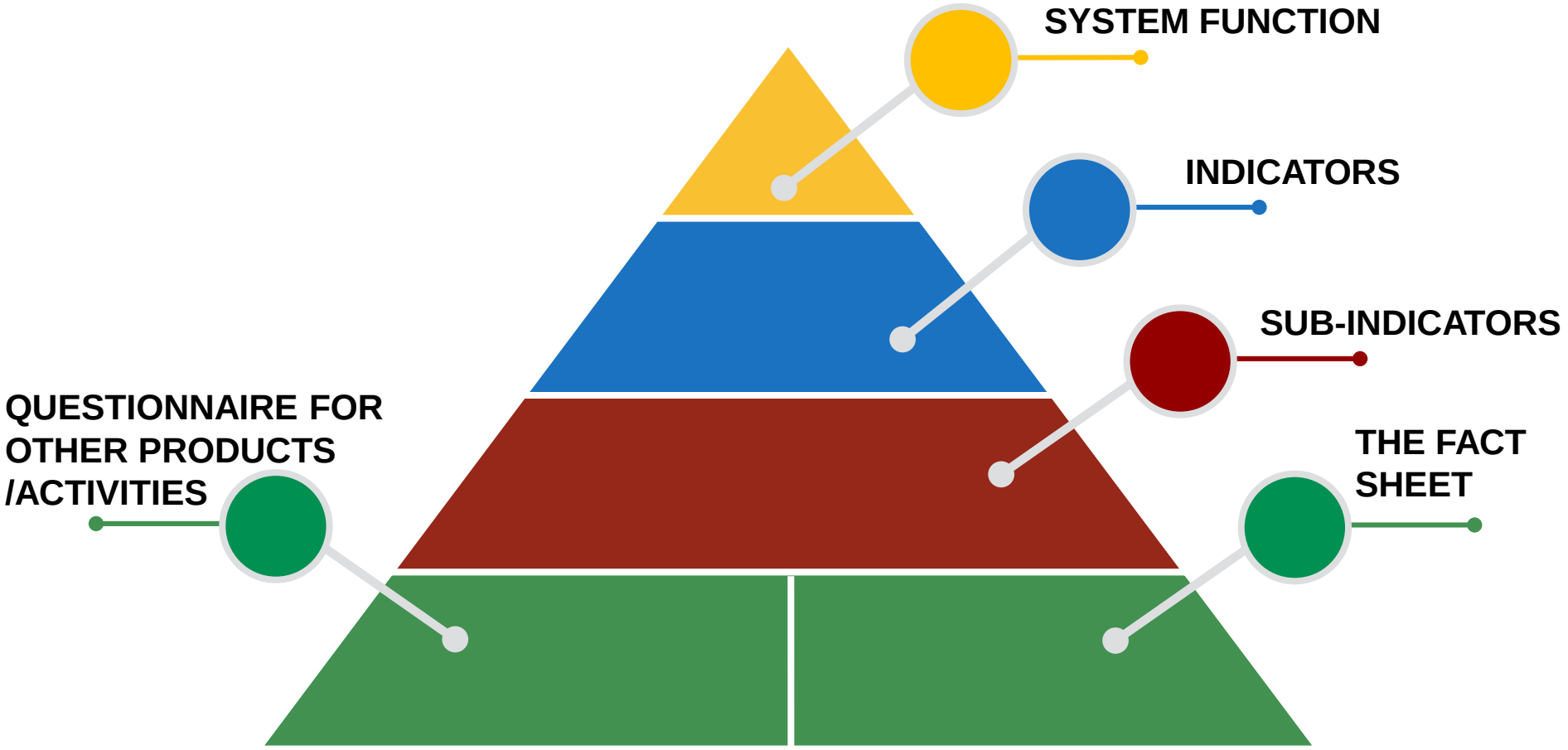
- **Evaluate** — Evaluate national regulatory systems
- ***Tools*** — Apply WHO evaluation tools
- **Performance** — Generate and analyze evidence of regulatory system performance
- **IDPs** — Facilitate the formulation and implementation of institutional development plans
- **Technical support** — Provide technical support to national regulatory authorities and governments

WHO NRA 5 step capacity building



WHO Global Benchmarking Tool

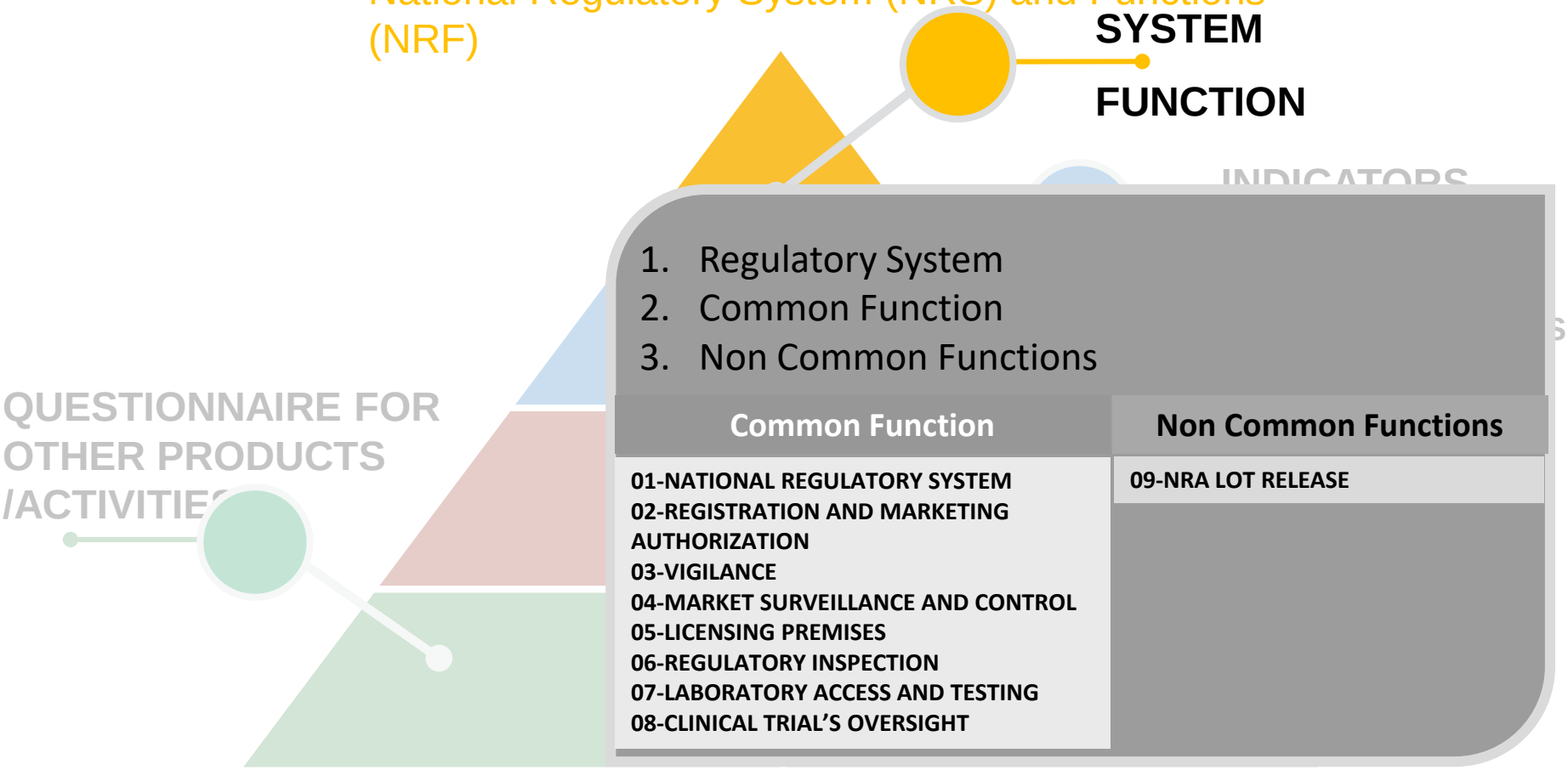
Structure/Hierarchy



WHO Global Benchmarking Tool

Structure/Hierarchy

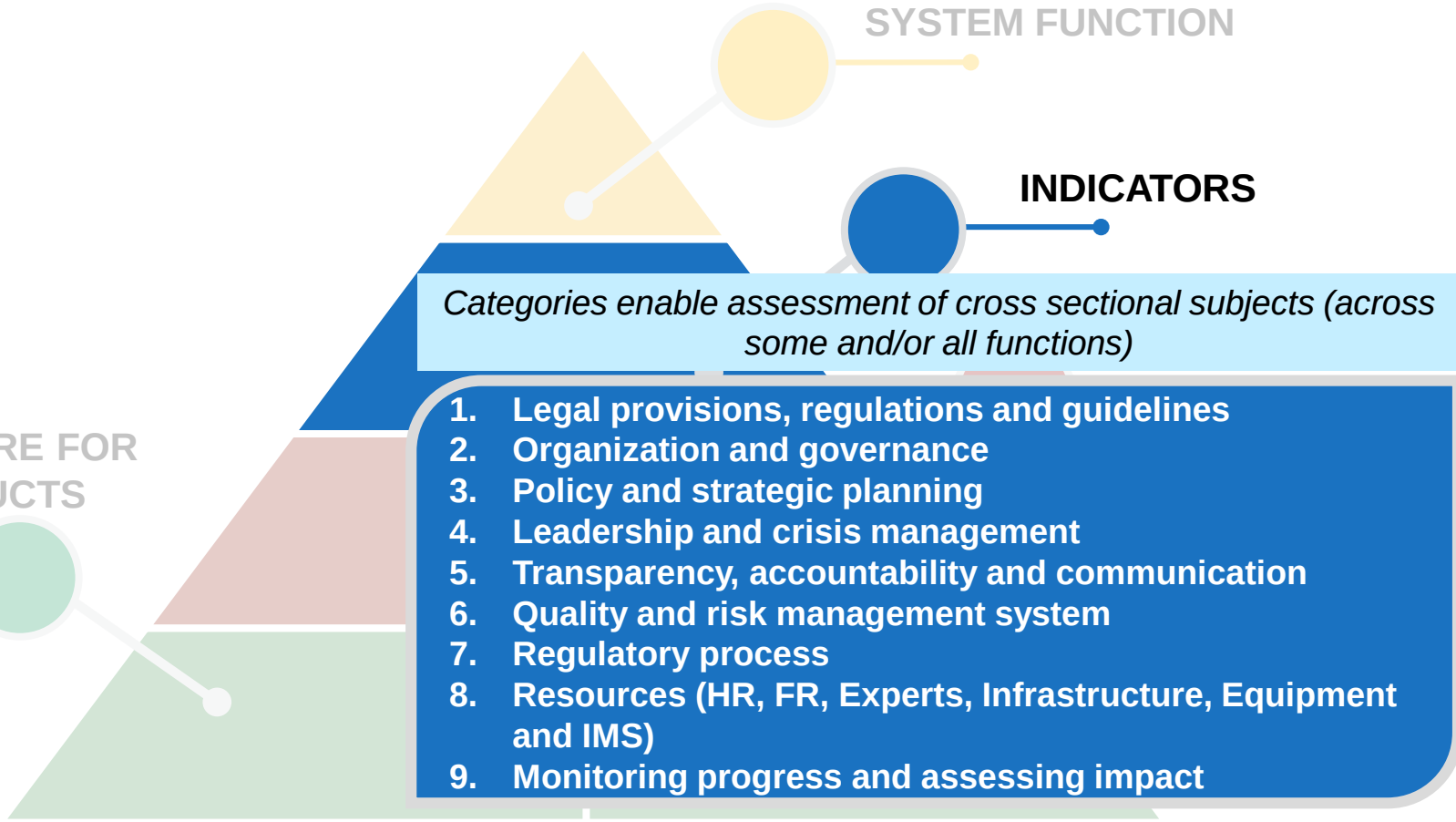
National Regulatory System (NRS) and Functions (NRF)



WHO Global Benchmarking Tool

Structure/Hierarchy

Indicators Categorization (cross cutting subjects)



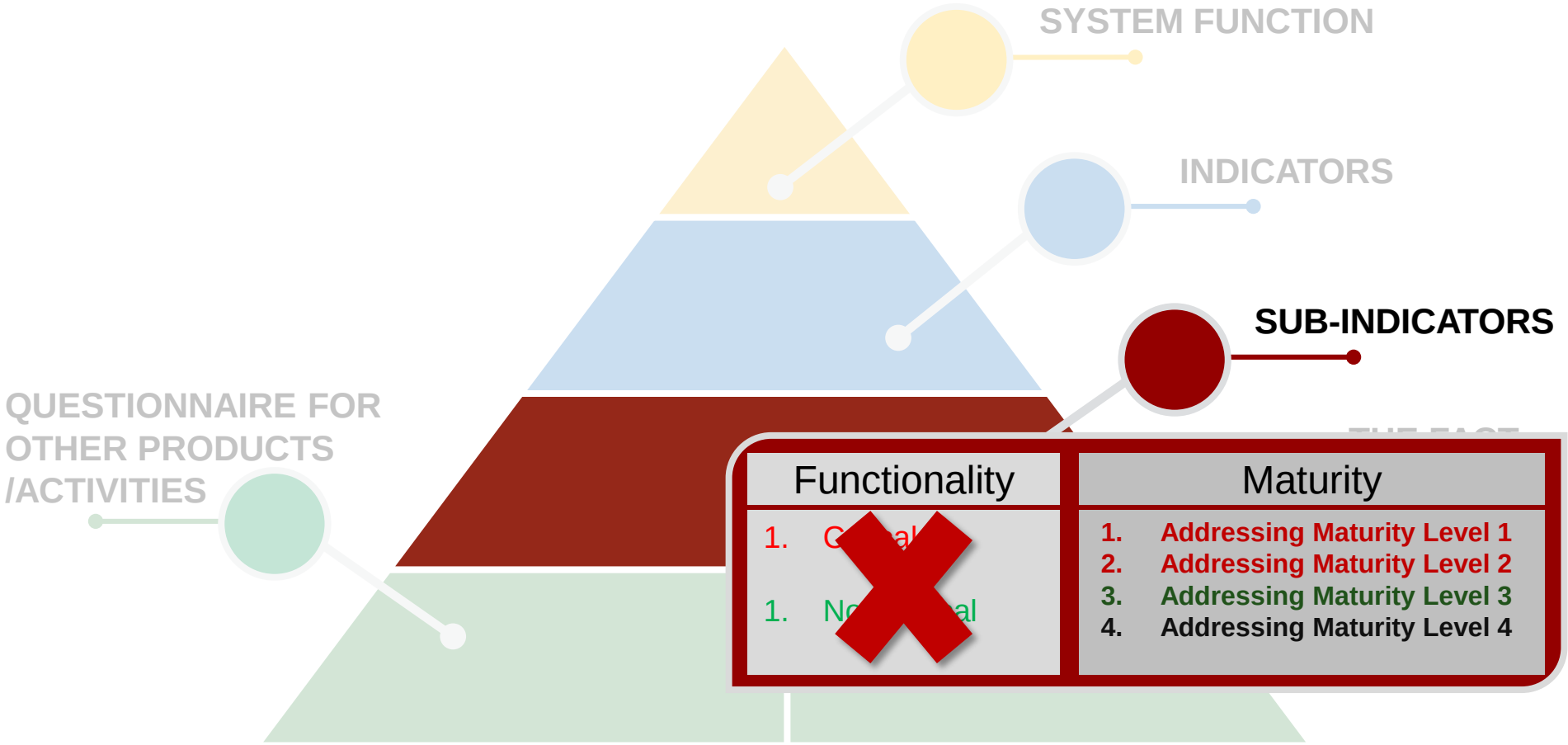
Categories enable assessment of cross sectional subjects (across some and/or all functions)

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**

WHO Global Benchmarking Tool

Structure/Hierarchy

Sub-Indicators Categorization

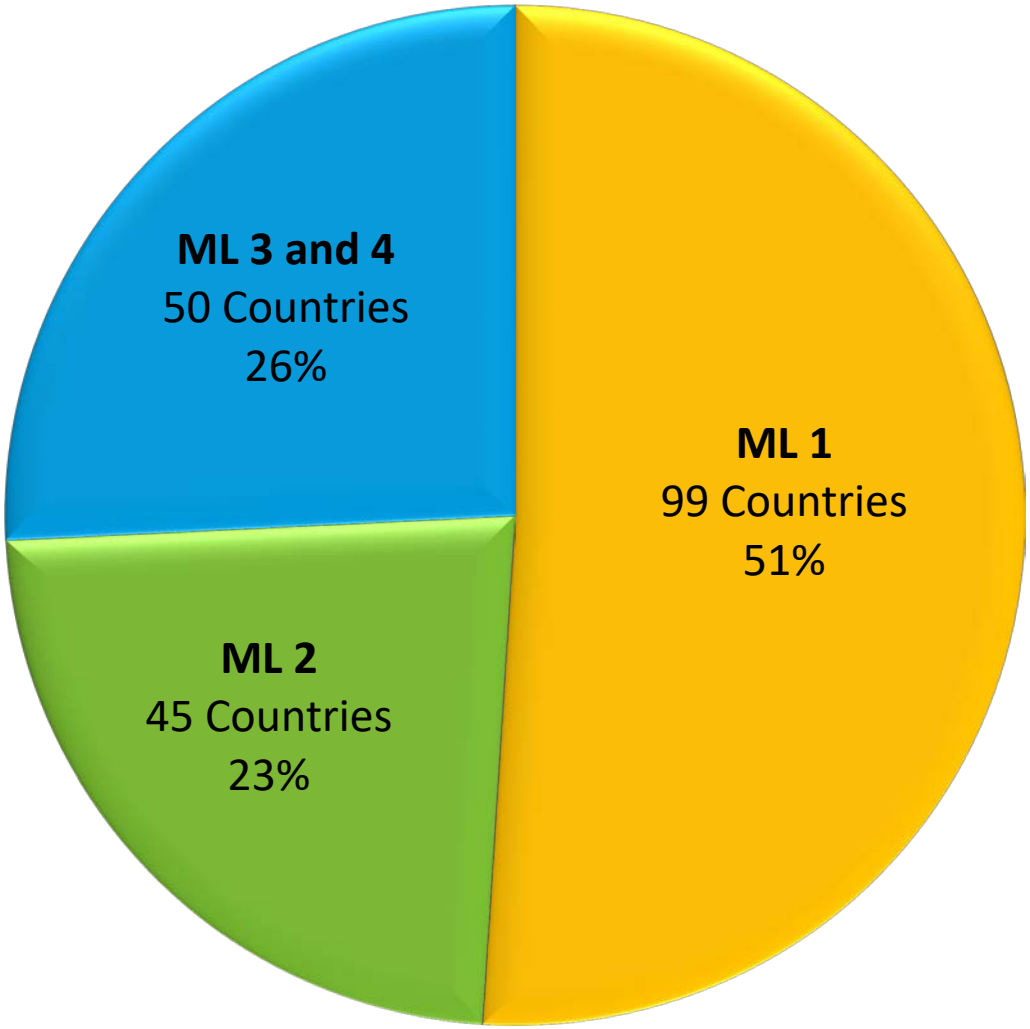


WHO GBT Performance Maturity Levels

ISO 9004

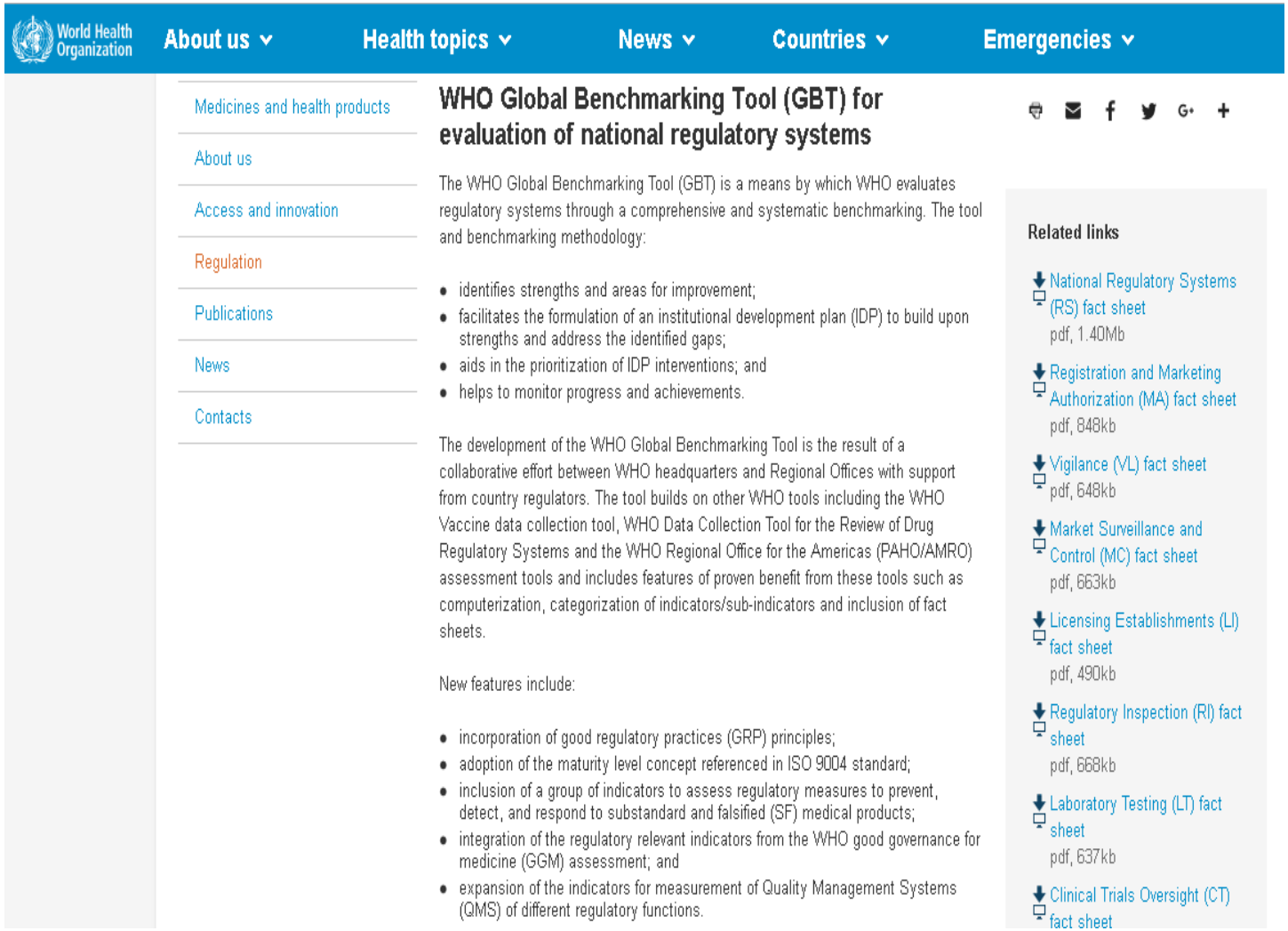
1	2	3	4
No formal approach	*Reactive approach*	*Stable formal system approach*	*Continual improvement emphasized*
Some elements of regulatory system exist	Evolving national regulatory system that partially performs essential regulatory functions	Stable, well-functioning and integrated regulatory system	Regulatory system operating at advanced level of performance and continuous improvement
Can be consider as functional if rely on other regulators for some specific functions		Target of WHA Resolution 67.20	Advanced/reference regulators

Overall regulatory systems' maturity level of WHO Member States



(Updated 15 May 2018)
WHO MVP/RSS/CRS

Public consultation of WHO GBT Revision VI



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 reliance 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

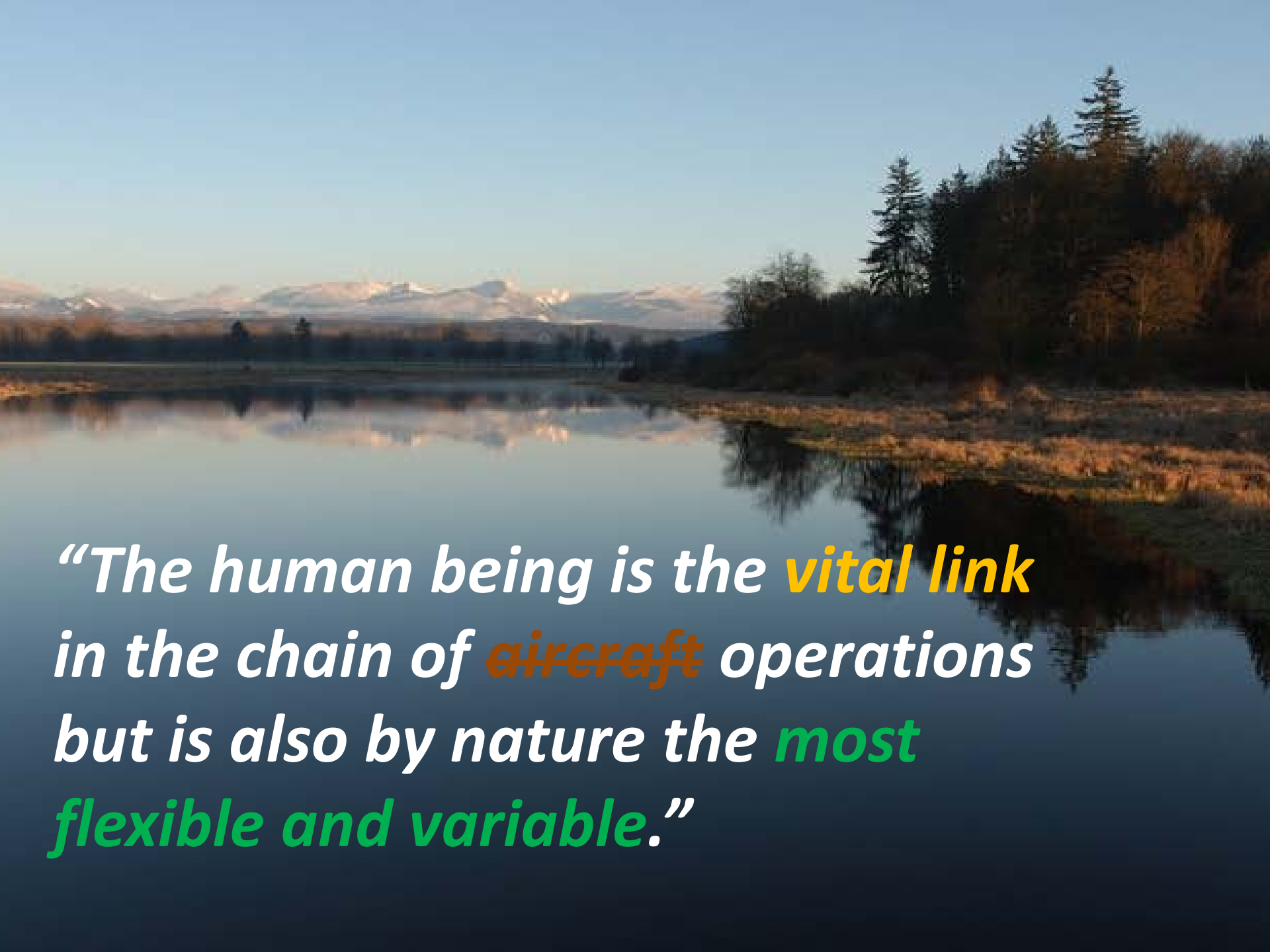
WLAs

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.

Objective

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**

Global Competency Model

World Health Organization

Define occupational credential

Specific to the regulation of medical products

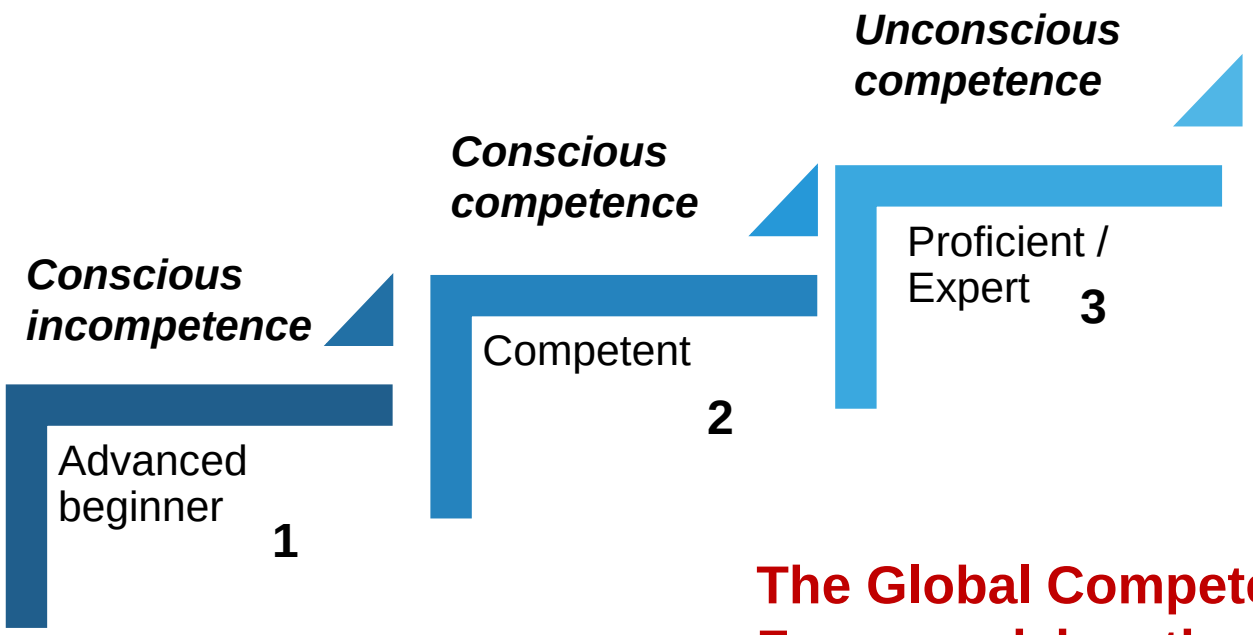
Foundation for success in the world of work

C. Occupation-related competencies

B. Generic competencies (CORE)

A: Mandatory

Stages of Professional Development / Skill Acquisition



The Global Competency Framework has three levels

Five-stage model of adult skill acquisition., Dreyfus, 2004.
RAPS: uses 4 professional levels for regulatory affairs professionals
EMA: uses 3-grade level for quality assessors
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/11/WC500134496.pdf

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

WLA: Evaluation framework

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