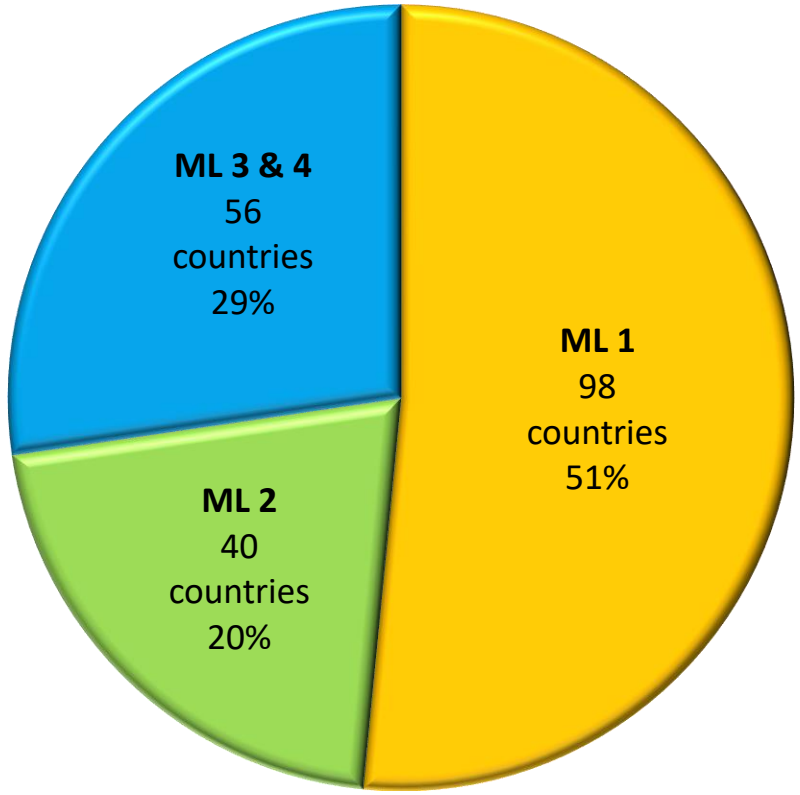
WHO Regulatory Systems Strengthening Program

Overall regulatory systems' maturity level of WHO Member States and major challenges



June 2022

SDG 3 – Target 3.8

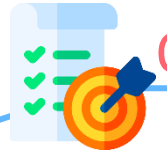
Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and **access to safe, effective, quality and affordable essential medicines and vaccines for all**.

Resolution WHA 67:20 – RSS for medical products

World Health Organization

- **Adopted in May 2014**
  - ✓ Recognized the importance of strong regulatory systems to a well-functioning healthcare system and the attainment of health-related SDGs and UHC

WHO supports Member States in reaching and sustaining effective regulatory oversight of medical products through the regulatory systems strengthening (RSS) programme



Objectives of the RSS programme

- *Build capacity in Member States consistent with good regulatory practices*
- *Promote regulatory cooperation, convergence and transparency through networking, work-sharing and reliance*

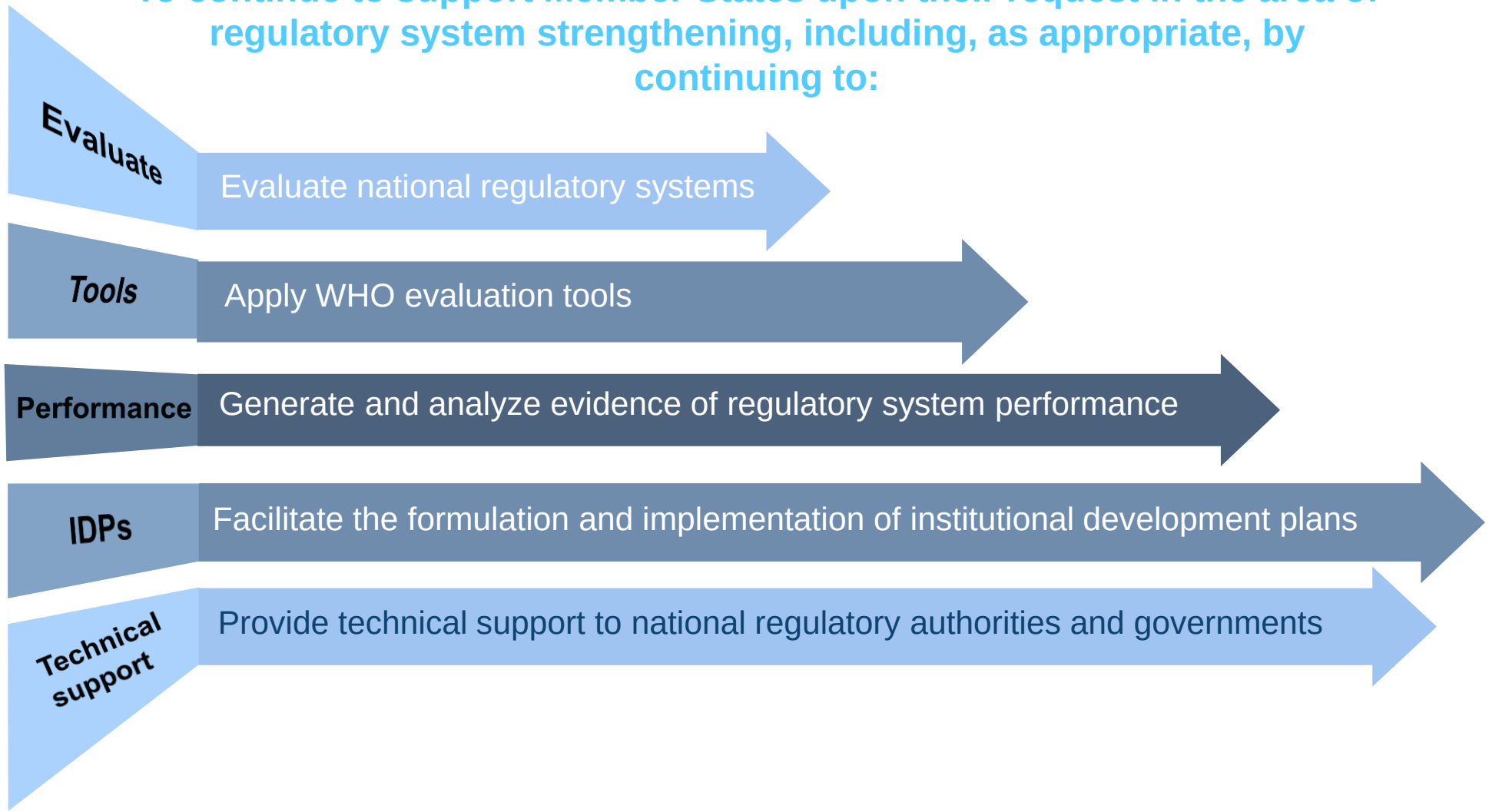
Ultimate goal

- ***Promote access to quality assured medical products***

WHA Resolution 67.20

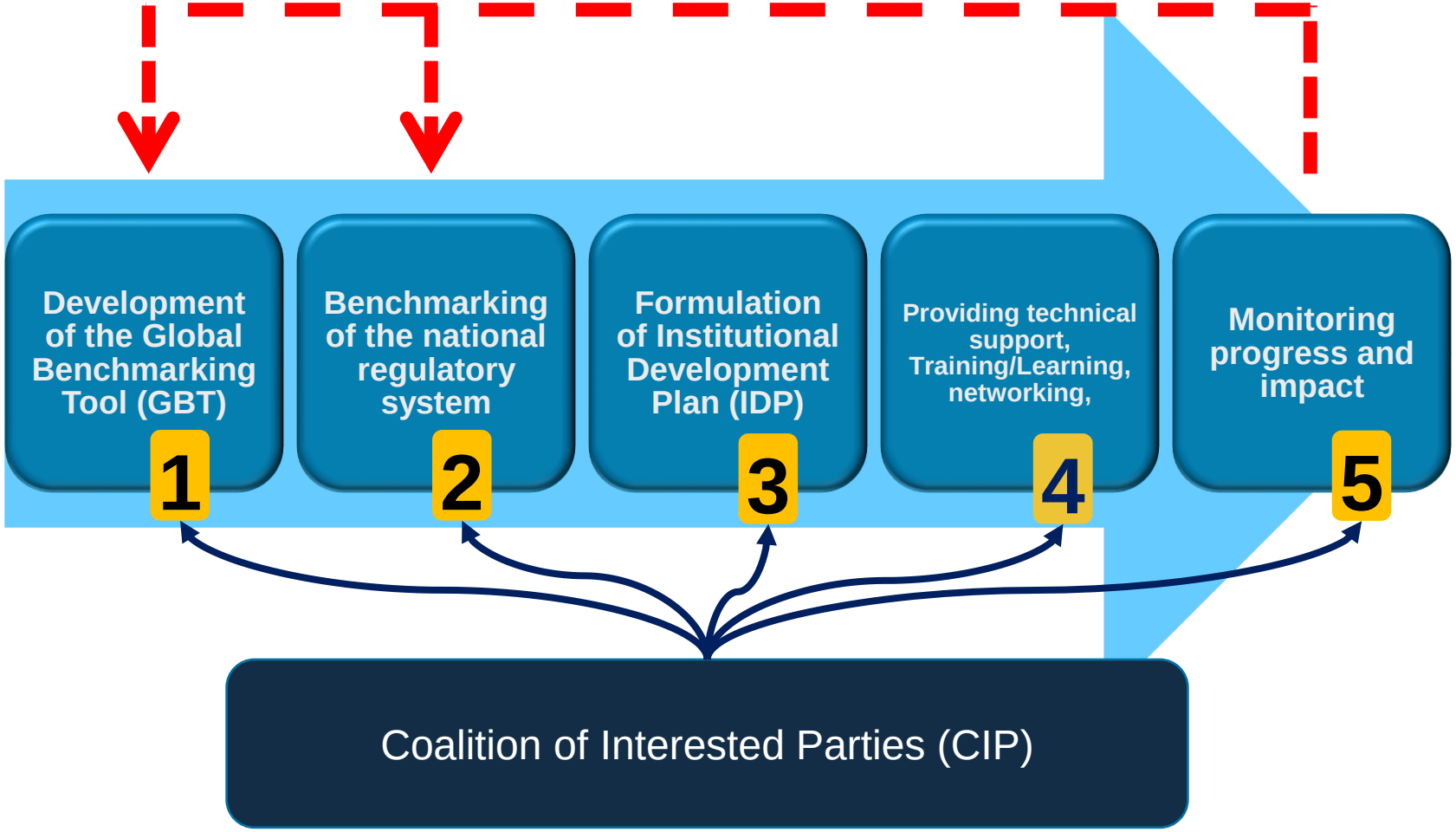
What WHO should do

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



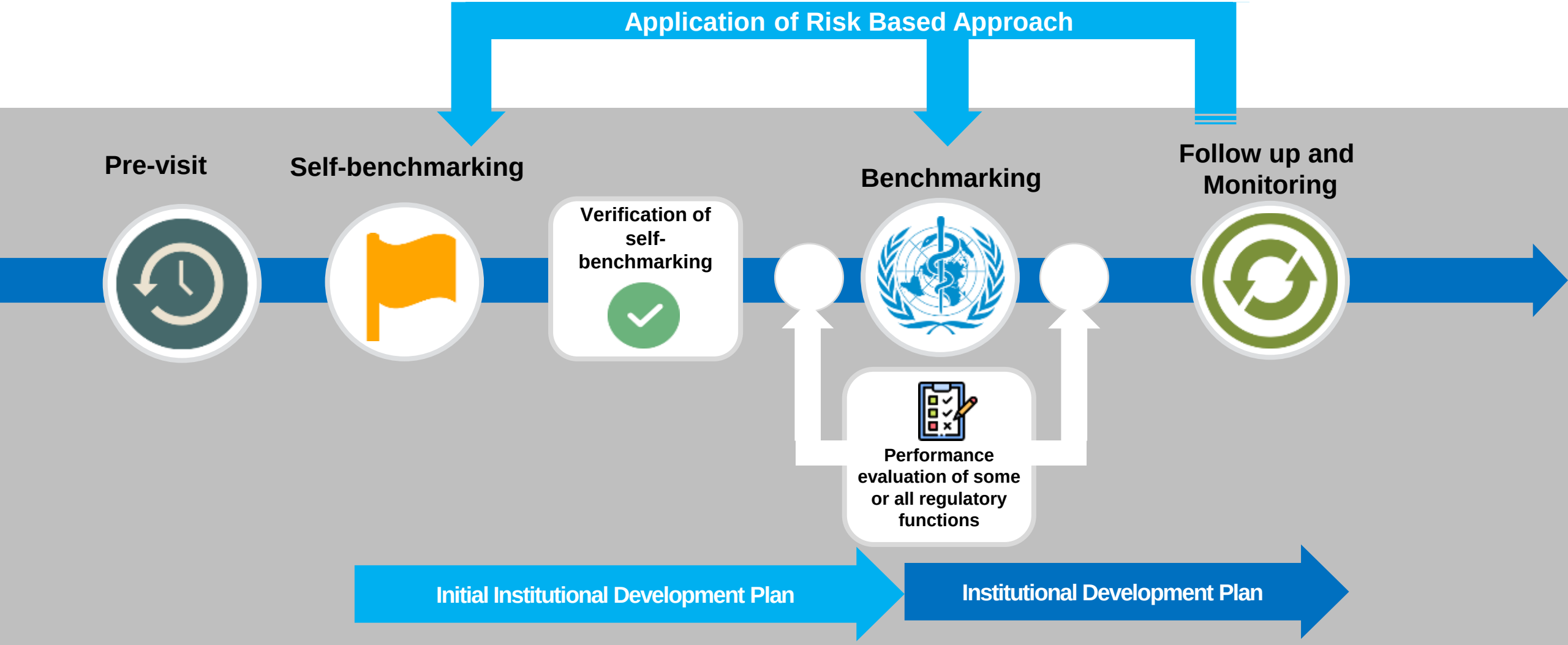
WHO Five-Step Capacity Building Model for National Regulatory Authorities (NRAs)

As per Resolution WHA 67.20 on Regulatory Systems Strengthening (2014)



- **Stable, well functioning and integrated regulatory system**
- **Eligibility for vaccine PQ**
- **WHO listed authorities (WLA)**

Benchmarking process



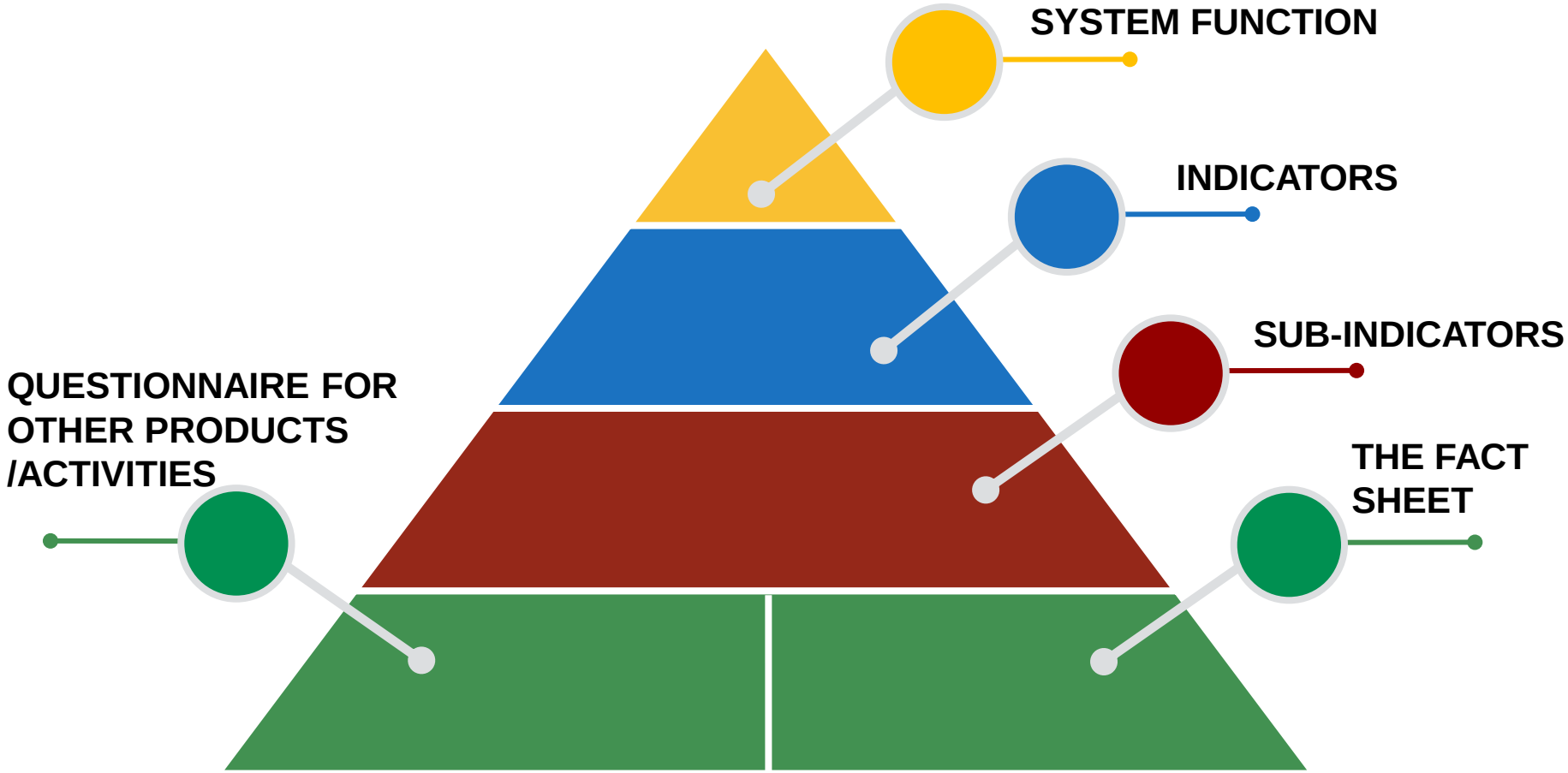
World Health Organization

WHO GBT Performance Maturity Levels

	1	2	3	4
ISO 9004	*No formal approach*	*Reactive approach*	*Stable formal system approach*	*Continual improvement emphasized*
WHO GBT	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 ensure the quality of products if rely on ML 3/ ML 4 regulatory systems		Target of WHA Resolution 67.20	Advanced and well-resourced regulatory systems

WHO Global Benchmarking Tool

Structure/Hierarchy

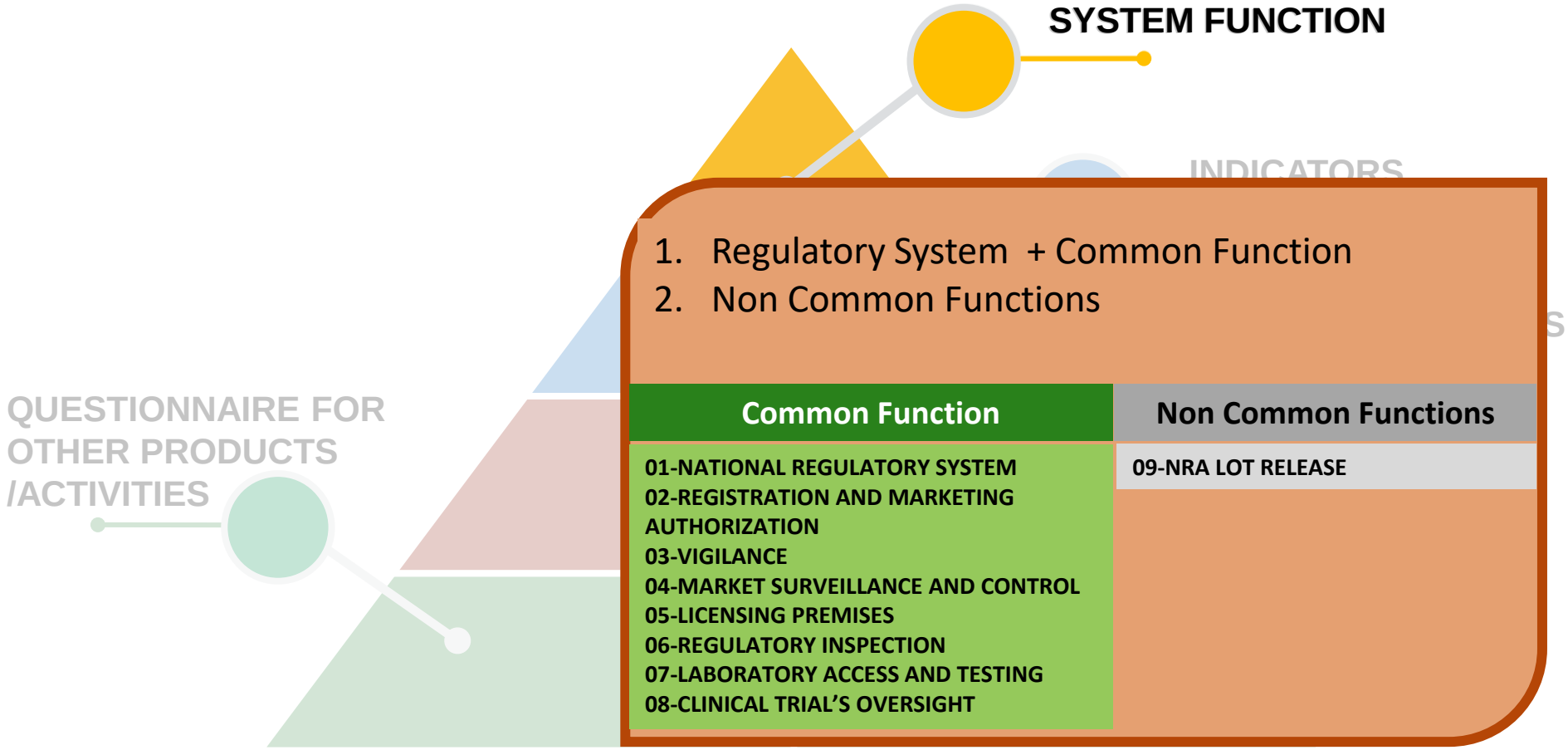


WHO Global Benchmarking Tool

World Health Organization

Structure/Hierarchy

National Regulatory System (NRS) and Functions (NRF)



Updated Figures of the WHO GBT revision VI

World Health Organization

Item / Function	RS	MA	VL	MC	LI	RI	LA	CT	LR	Grand Total
Number of Sub-Indicators	60	35	26	27	19	26	28	30	17	268
Sub-Indicators measuring maturity level 1	4	6	5	3	2	3	2	2	1	28
Sub-Indicators measuring maturity level 2	7	2	3	4	1	2	2	8	3	32
Sub-Indicators measuring maturity level 3	27	23	14	15	13	13	18	17	11	152
Sub-Indicators measuring maturity level 4	22	4	4	5	3	8	6	3	2	56

Minimal capacity

Advanced/reference NRAs

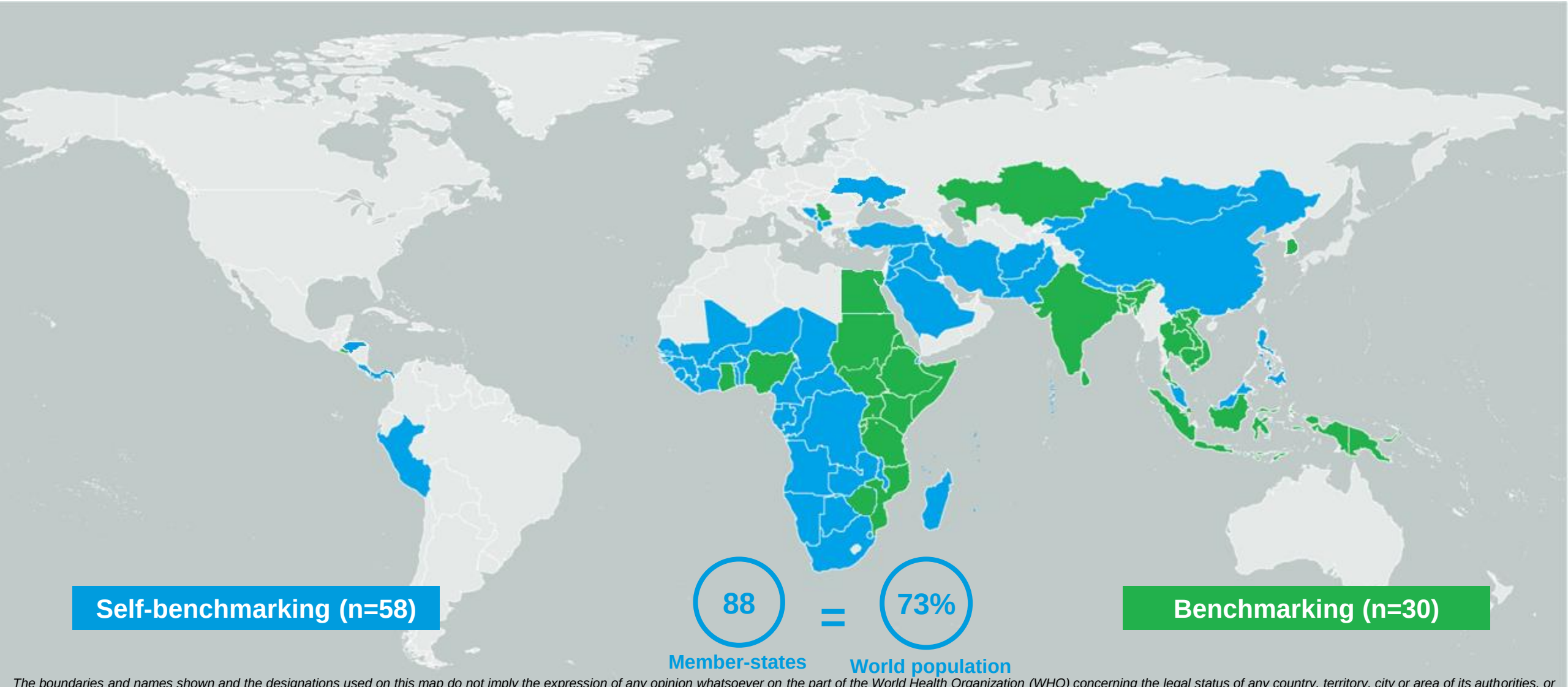
Flexible algorithm for determining ML

ML	Percentage of implementation of sub-indicators attained			
	% of implemented sub-indicators	% ongoing implementation sub-indicators	% partially implemented sub-indicators	% of non-implemented sub-indicators
1	Up to 100% of ML1	Up to 100% of ML1		Up to 100% of ML1
2	95% of ML1+ML2	5% of ML1+ML2		0%
3	100% of ML1+ ML2 and 90% of ML3	10% ML3		0%
4	100% of ML1+ ML2+ML3 and 80% of ML4	20% ML4		0%

In case the percentage is less than or equal to 1 sub-indicator for a particular function, it should be rounded up to 1 sub-indicator for that function provided that the total percentage across all functions does not exceed the stated one, as explained in the examples below.

Member States participated in WHO Regulatory System Strengthening Program and benchmarked against GBT indicators between 2016 - May 2022

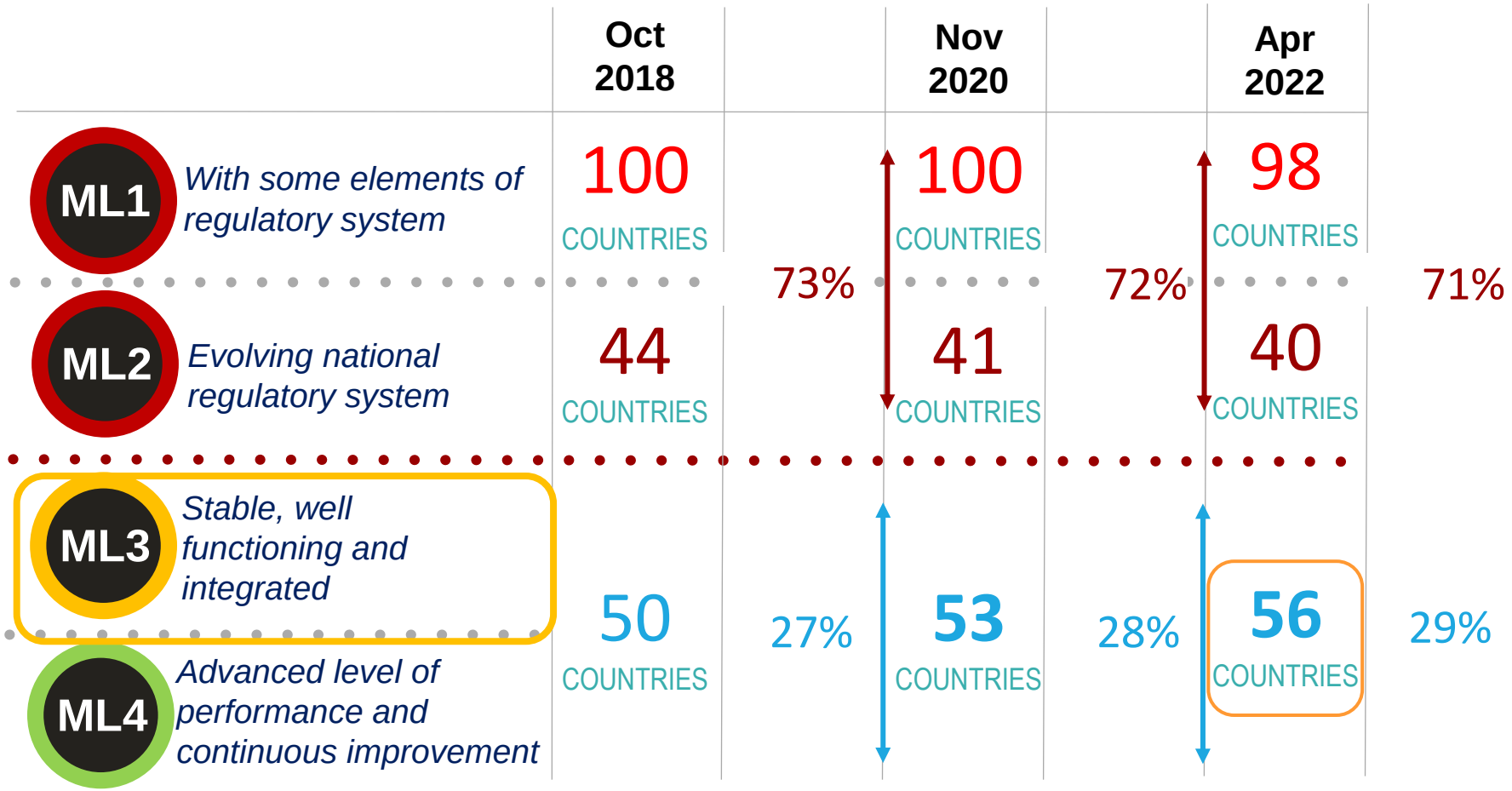
World Health Organization



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 (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.

Global status of national regulatory systems, April 2022

World Health Organization



Vaccines developed in countries with weak regulatory systems, i.e., ML1/ML2, are not eligible for WHO EUL or Prequalification

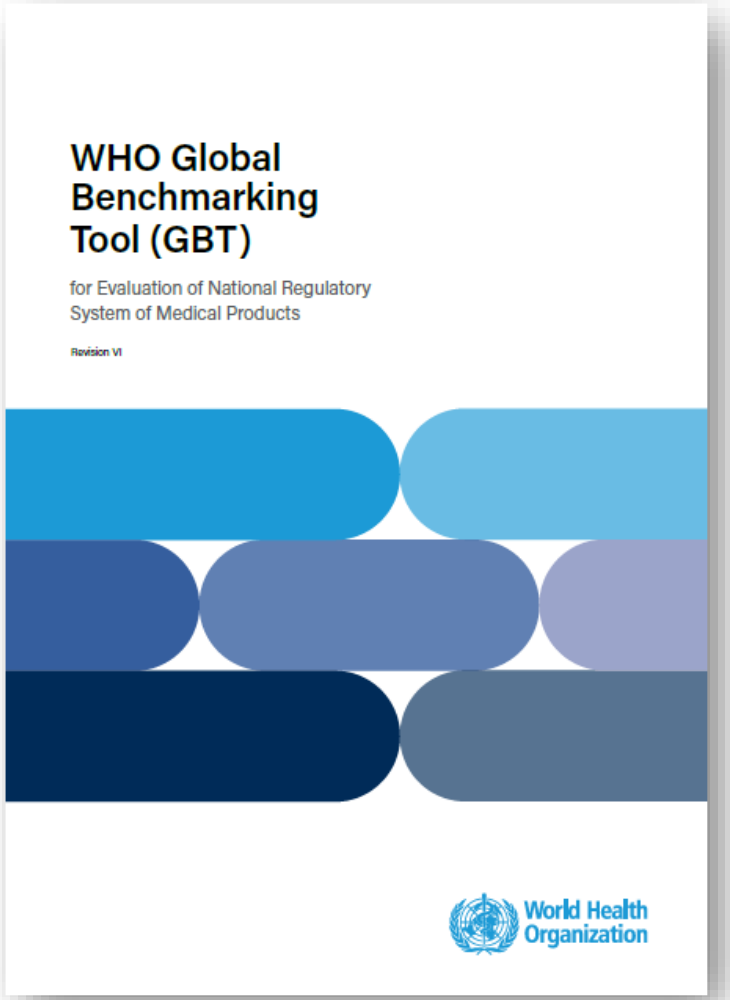
Singapore medicines regulator world's first to achieve the highest maturity level (ML4) following assessment (28 Feb 2022)

ML3 **GOAL of WHA Resolution 67.20**

ML: *(regulatory system) maturity level*

Egypt and Nigeria announced as ML 3 in March 2022

WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems of medical products: Revision VI



Link: https://apps.who.int/iris/handle/10665/341243

+

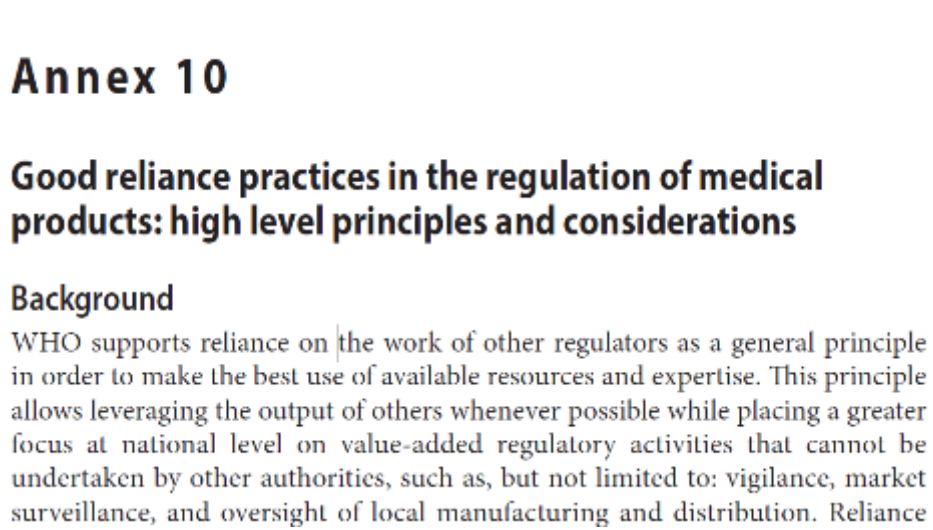
Blood (Nov 2019)

Medical Devices (Q2 2022)

Link: https://www.who.int/tools/global-benchmarking-tools

WHO Good Regulatory Practices and Good Reliance Practices

55th report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP)

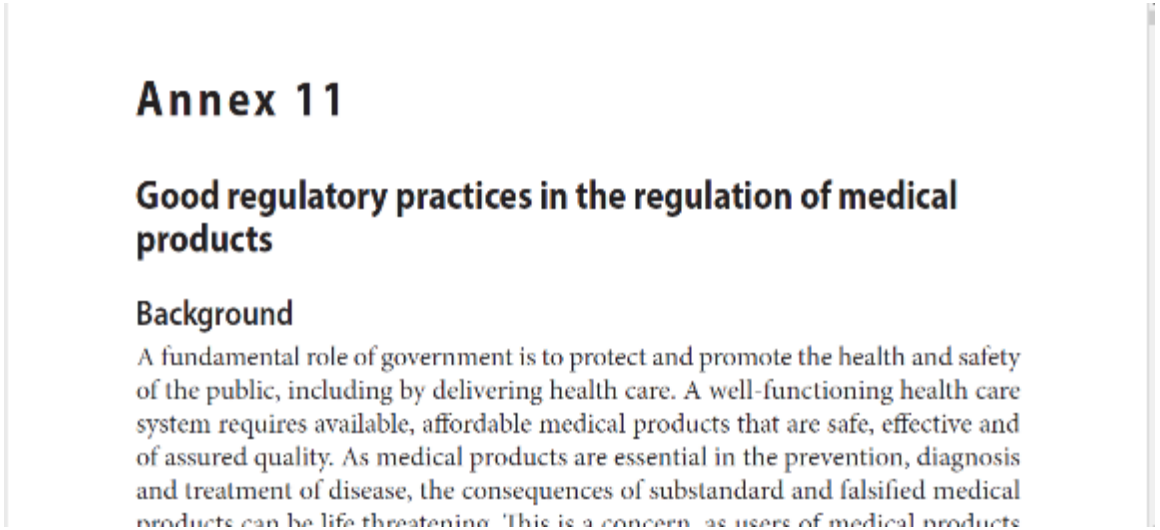


Annex 10

Good reliance practices in the regulation of medical products: high level principles and considerations

Background

WHO supports reliance on the work of other regulators as a general principle in order to make the best use of available resources and expertise. This principle allows leveraging the output of others whenever possible while placing a greater focus at national level on value-added regulatory activities that cannot be undertaken by other authorities, such as, but not limited to: vigilance, market surveillance, and oversight of local manufacturing and distribution. Reliance



Annex 11

Good regulatory practices in the regulation of medical products

Background

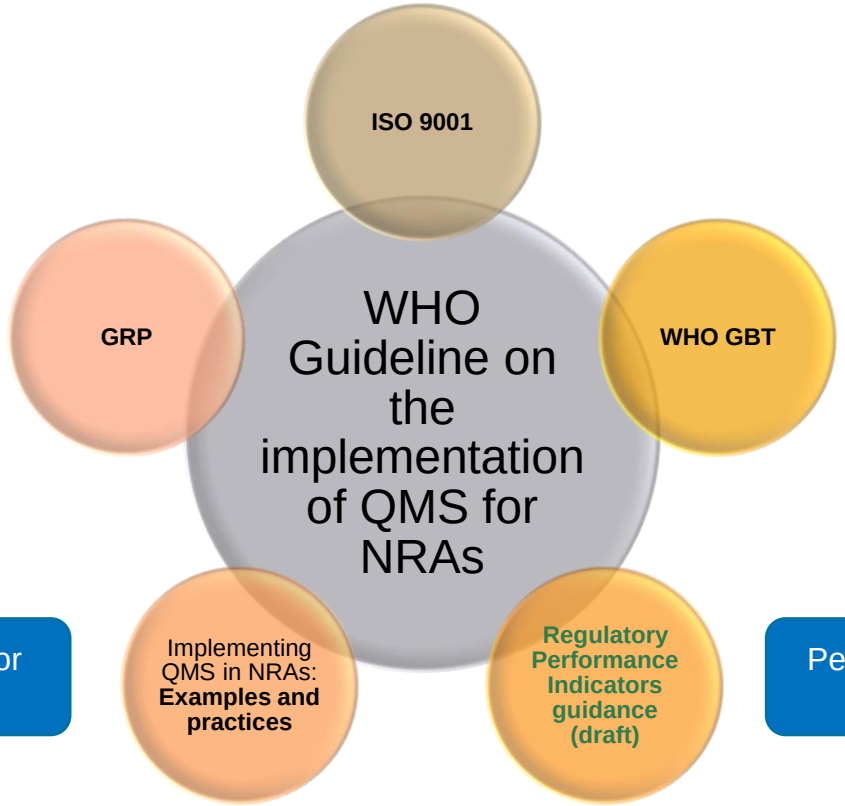
A fundamental role of government is to protect and promote the health and safety of the public, including by delivering health care. A well-functioning health care system requires available, affordable medical products that are safe, effective and of assured quality. As medical products are essential in the prevention, diagnosis and treatment of disease, the consequences of substandard and falsified medical products can be life threatening. This is a concern, as users of medical products

Link: https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations

WHO guideline on the implementation of QMS systems for national regulatory authorities - TRS 1025 - Annex 13

Link: https://www.who.int/publications/m/item/trs-1025-annex-13-qms-nra

Concept, principles and requirements



A robust and well-functioning quality management system one of the enablers of GRP

Regulatory Systems Strengthening

Additional guidance for implementation

Performance evaluation and improvement

Coalition of Interested Parties

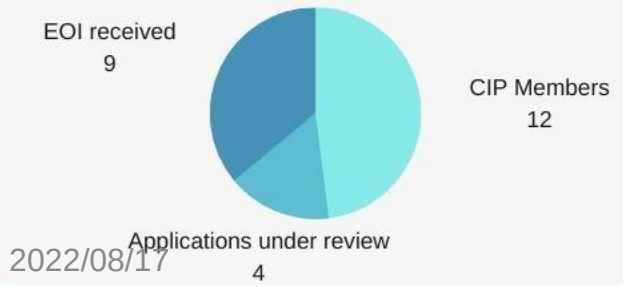
Establish and promote a unified strategic and coordinated approach to strengthening national and regional regulatory systems

Visit the CIP web platform: www.cip-network-rss.org

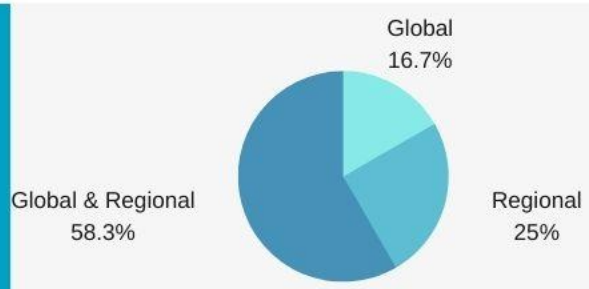
Contact the CIP Secretariat: cip_network@who.int

1	Academic institution
4	Government bodies
2	Intergovernmental organizations
3	Non-governmental organizations
1	Philanthropic organization
1	Umbrella regional or international business association

CIP MEMBERSHIP STATUS: MAY 2022



LEVEL OF ENGAGEMENT OF CURRENT CIP MEMBERS



75% PARTCIPANTS

25% OBSERVERS

WLA Framework

World Health Organization

01 Provide a transparent and evidence-based pathway for NRAs to be globally recognized

02 Promotes access and the supply of safe, effective and quality medical products by expanding pool of NRAs to be relied by WHO PQ

03 Optimizes use of limited resources by facilitating reliance

Policy document

Describes the purpose, definitions and high-level operating principles related to the evaluation and public listing of authorities

Link: https://www.who.int/publications/i/item/978924002344

Link: https://www.who.int/news-room/articles-detail/operational-guidance-evaluating-and-publicly-designating-regulatory-authorities-as-who-listed-authorities

Code of conduct at WHO events

World Health Organization

CODE OF CONDUCT

To Prevent Harassment, including Sexual Harassment, at WHO events

PURPOSE

WHO is committed to enabling events at which everyone can participate in an inclusive, respectful and safe environment. WHO events are guided by the highest ethical and professional standards, and all participants are expected to behave with integrity and respect towards all participants attending or involved with any WHO event.

APPLICABILITY

The Code of Conduct applies to any WHO event, which shall include meetings, conferences and symposia, assemblies, receptions, scientific and technical events, expert meetings, workshops, exhibits, side events and any other forum organized, hosted or sponsored in whole or part by WHO wherever it takes place, and any event or gathering that takes place on WHO premises whether or not WHO is organizing, hosting or sponsoring.

The Code of Conduct applies to all participants at a WHO event, including all persons attending or involved in any capacity in WHO event.

Any other entity responsible for a WHO event commits to implementing the Code of Conduct.

The Code of Conduct is not legal or prescriptive in nature. It supplements, and does not affect, the application of other relevant policies, regulations, rules and laws, including laws regulating the premises in which the WHO event takes place and any applicable host country agreements.

PROHIBITED CONDUCT

Harassment is any behaviour that is directed at another person and has the effect of offending, humiliating or intimidating that person; and the person engaging in the behaviour knows or reasonably ought to know would offend, humiliate or intimidate that other person. Harassment in any form because of gender, gender expression, gender identity, race, religion or belief, nationality, ethnic or social origin, age, sexual orientation, marital status, disability, language or any other reason is prohibited at WHO events.

Sexual harassment is a specific type of prohibited conduct. Sexual harassment is any unwelcome conduct of a sexual nature that might reasonably be expected or be perceived to cause offence or humiliation. Sexual harassment may involve any conduct of a verbal, nonverbal or physical nature, including written and electronic communications, and may occur between persons of the same or different genders.

Examples of sexual harassment include, but are not limited to:

Making derogatory or demeaning comments about someone's sexual orientation or gender identity	Name-calling or using slurs with a gender/sexual connotation	Making sexual comments about appearance, clothing or body parts	Making comments about or rating a person's attractiveness
Asking for sexual favours or repeatedly asking a person for dates	Staring in a sexually suggestive manner	Unwelcome touching, including pinching, patting, rubbing or purposefully brushing up against a person	Making inappropriate sexual gestures, such as pelvic thrusts
Sharing sexual or lewd anecdotes or jokes	Sending sexually suggestive communications in any format	Sharing or displaying sexually inappropriate images or videos in any format	Attempted or actual sexual assault, including rape

COMPLAINT PROCESS

A participant who feels that they have been harassed at a WHO event may report the matter to the organizer of the WHO event or relevant security authority, and a participant who witnesses such harassment should make such a report. The organizer of the WHO event will be expected to take appropriate action in accordance with its applicable policies, regulations and rules.

Examples of appropriate action may include, but are not limited to:

Requesting the offender to immediately stop the offending behavior	Suspending or terminating the offender's access to the WHO event or refusing registration at future WHO events, or both	Conveying the complaint to any investigative or disciplinary authority with jurisdiction over the person accused of harassment	Conveying a report to the employer or entity with jurisdiction over the person accused of harassment for appropriate follow-up action

The victim of alleged harassment may also seek help from other relevant authorities, such as the police, bearing in mind the applicable legal framework. A participant should never knowingly make a false or misleading claim about prohibited conduct.

PROHIBITION OF RETALIATION

Threats, intimidation or any other form of retaliation against a participant who has made a complaint or provided information in support of a complaint are prohibited. WHO or other entity responsible for a WHO event will take any reasonable appropriate action needed to prevent and respond to retaliation, in accordance with its applicable policy, regulations and rules.

World Health Organization

Regulatory Systems Strengthening
Regulation of Medicines and Other Health Technologies
Essential Medicines and Health Products
World Health Organization (Geneva, Switzerland)
Office: +41 (0)22 791 4381

Thank you

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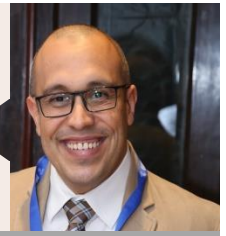

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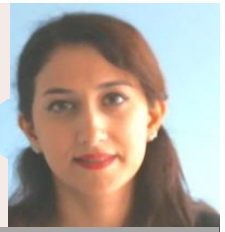

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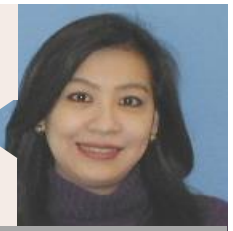

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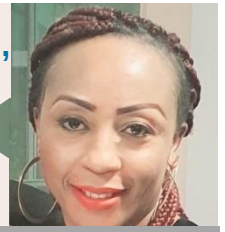

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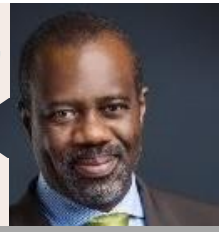

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