Global Health Supplies:
Paradigm Shifts in Market Authorization, Procurement and Supply Chains Approaches

Joint UNICEF, UNFPA and WHO meeting with manufacturers and suppliers of
in vitro diagnostic products, vaccines & immunization devices, finished pharmaceutical products, active pharmaceutical ingredients, contraceptive devices and vector control products
28 November - 01 December 2022, UN City, Copenhagen, Denmark

WHO Listed Authorities (WLA) and promoting reliance

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Regulatory Updates

Context

- **Resolution WHA 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

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***




Objectives of WLA initiative

01 To provide a transparent and evidence-based pathway for RAs to be globally recognized

02 To promote access and the supply of safe, effective and quality medical products

03 To optimize use of limited resources by facilitating reliance

Policy document:

The Policy 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/9789240023444




WHO Listed Authorities framework

latest publications

MARCH 2022 **PEF Manual**

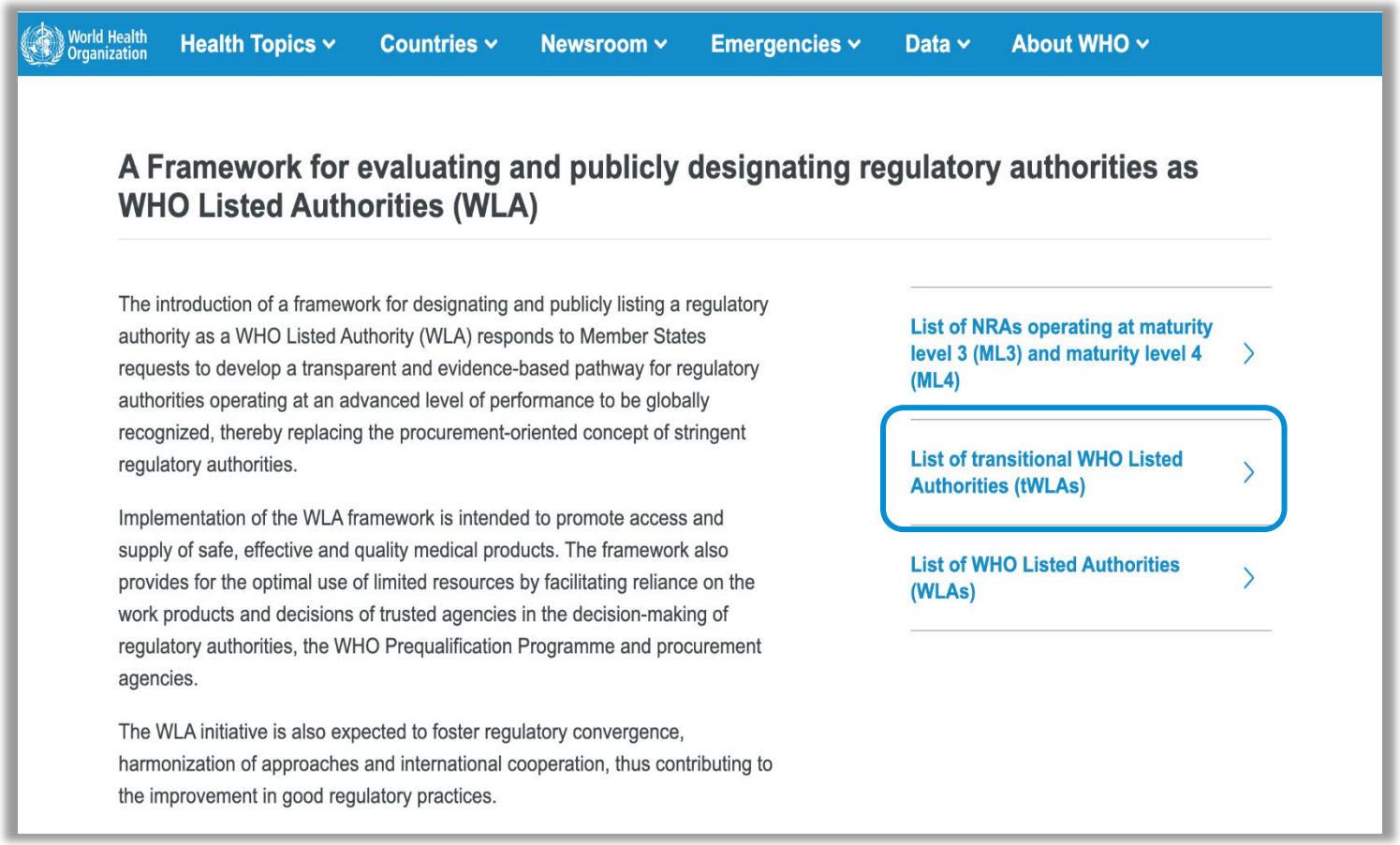
MARCH 2022 **WLA Operational Guidance**

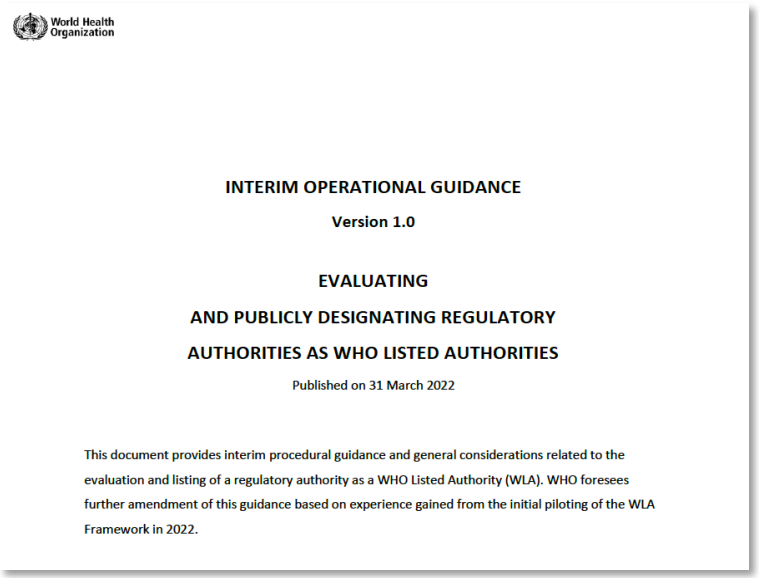
JULY 2021 WLA Policy

MAY 2019 WLA Concept note




WLA initiative launched on 31st March 2022





link: *Interim Operational guidance for WLA*

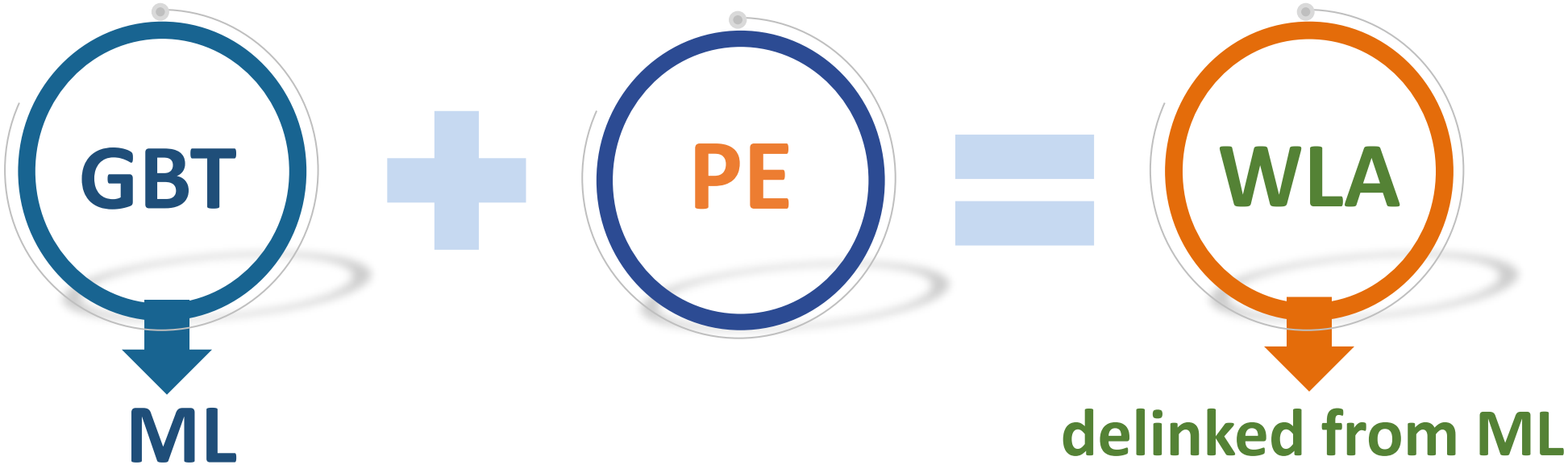
link: *Interim Manual for performance evaluation of WLA*

A combined approach to achieve listing

WLA builds upon GBT

A WHO Listed Authority (WLA) is a regulatory authority or a regional regulatory system which has been documented to comply with all the relevant indicators and requirements specified by WHO for the requested scope of listing based on

an **established benchmarking (GBT)** **AND** a **performance evaluation (PE) process**



WLA operating principles

ELIGIBILITY

01 Voluntary process initiated by a request from a member state

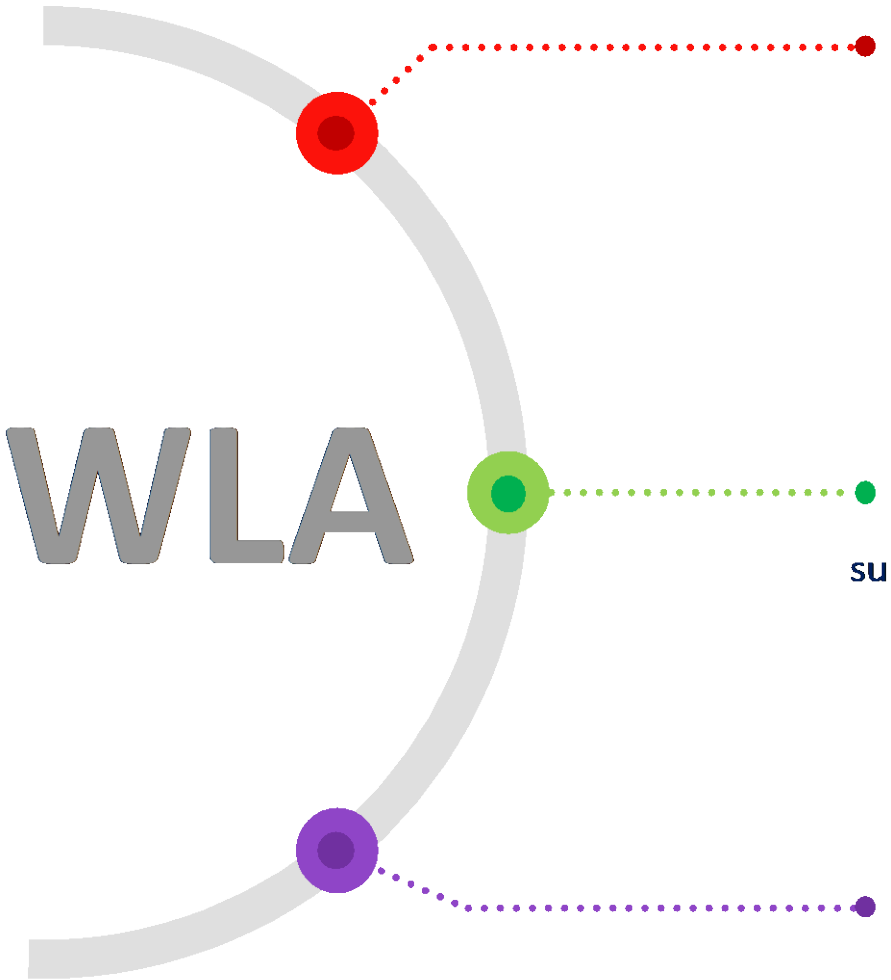
02 National Regulatory Authority (NRA) or Regional Regulatory System (RRS) are eligible

03 Regulatory Authorities must have attained overall Maturity Level 3 to be eligible for the PE process

04 Transitional WLAs are all eligible for the PE process

Operating principles

LISTING

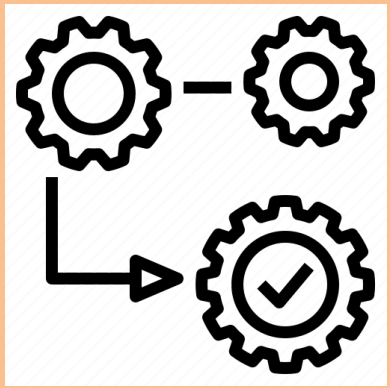


A **regulatory authority is publicly listed as a WLA** following successful completion of the performance evaluation process

Listing will include **scope of the designation** (functions and product streams), **evidence reviewed, process undertaken** to support the listing and period of validity of the listing

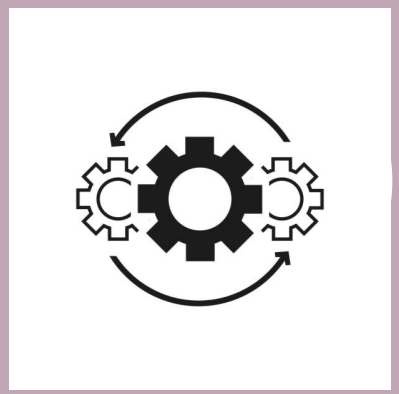
Listing will be initially valid for a **defined period of years**, provided no changes have taken place that could negatively impact the WLA listing

Piloting the three pathways to WLA with three RAs



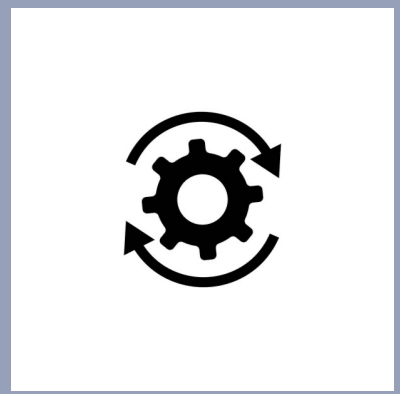
Standard

- GBT assessment conducted and ML4 attained
- PE indicators and tools under evaluation



Streamlined

- GBT and PE indicators evaluated
- PE tools ongoing



Abridged

- Abridged tool under evaluation before piloting can be conducted

Comments from assessors and assessees, currently under collection, will inform the revision of Interim OpG and Interim Manual for PE, by Q1 2023

Risk-based performance evaluation pathways

Evaluation pathway		Eligibility	Evaluation methodology
Transitional arrangements (tWLAs)	Abridged	SRAs for medicines and highly performing NRAs for vaccines	1. RA self-assessment against pre-selected GBT and PE indicators that primarily target GRP and QMS 2. WHO desktop review of self-assessment report
	Streamlined	ML3 and ML4 RAs (medicines and/or vaccines)	1. RA self-assessment against pre-populated GBT, if needed, as well as PE indicators* 2. WHO desktop review of self-assessment report 3. WHO assessment against PEF**
		Regional reference RAs of the Americas (medicines and/or vaccines)	1. RA self-assessment against pre-populated GBT as well as PE indicators 2. WHO desktop review of self-assessment; may involve an audit against selected GBT indicators to verify findings. 3. WHO assessment against PEF
		Functional RAs (vaccines)	
Routine arrangements (All other authorities)	Standard	Overall ML3 or ML4 RAs (medicines and/or vaccines) through GBT benchmarking	1. RA self-assessment against PEF indicators (GBT ML4 + PE) 2. WHO desktop review of self-assessment report 3. WHO assessment against PEF

* The need for self-assessment against pre-populated GBT is dependent on outcome and validity of the earlier benchmarking.
** PEF consists of an audit of mandatory ML4 + PE indicators + evaluation of selected regulatory functions using PE tools

WLA process steps and estimated timelines

Calendar days		Responsibilities	
		WHO	RA
1. Evaluation of Expression of Interest	30	✓	N/A
2. Agreement on scope of listing and evaluation plan	60	✓	✓
3. Performance evaluation and report	60 – 180*	✓	✓
4. Technical WLA Advisory Group (TAG-WLA) opinion	60	✓	N/A
5. Notice of Listing Decision (NOLD) and publication on WHO website	60	✓	N/A

*Depending on the performance evaluation pathway, scope of listing and available evidence.

Potential Benefits of WLA framework

Enable efficient use of regulatory resources

by providing a robust framework to promote **trust, confidence** and **reliance**

Encourage continuous improvement of regulatory systems and **regulatory convergence**

Help procurement decisions

on medical products by UN and other agencies, as well as countries (especially LMIC)

Contributes to PQ programme

by expanding the pool of trusted regulatory authorities

Fosters health equity

by enabling an environment for innovation and local production, and accelerating access to medical products




Ongoing works and next steps

Revision of OpG — Reflection of comments received during the public consultation

TAs — Drafting Transitional Arrangements (TAs) for the interim List of NRAs

Consultative meetings on TAs

TAG-WLA Open call

Finalization of OpG and tWLA

Piloting of framework and revision of OpG

Publication and translation

Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec

2022




THANK YOU

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