Certified for Success: Using the CEP Procedure to elevate quality and drive trust

23-24 September 2025, Budapest, Hungary

Keynote Speech: Building Trust in a Challenging Public Health Environment

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Navigating the current public health crisis

Navigating health financing cliffs: a new era in global health

An era in global health, inaugurated in 2000 by the UN Millennium Declaration,[1] has passed. This era saw large increases in domestic spending on health and official development assistance for health,[2] the creation of new global health institutions, such as the Global Fund and Gavi, and impressive progress in child mortality and infectious disease epidemic control.[3] The sudden passing of this era, triggered in early 2025 by rapid reductions in development assistance for health (by US, European, and other large external funders), has exacerbated existing pressures on domestic health spending (which decreased between 2021 and 2022 per capita across all countries for the first time since 2000[3]) and led to dramatic health financing cliffs.

Domestic health financing constraints—increasing debt servicing costs, poor economic growth following accounted for almost a third of external health funding in 2023.[4]

The question is whether countries, already off-track on the universal health coverage targets of the Sustainable Development Goals,[7] can navigate these health financing cliffs to sustain health services. The potential for reversal in hard-won progress and large-scale suffering and death is a severe crisis.[8] To fill these sudden gaps, countries can aim to increase current domestic and external resources, establish and mobilise new funding sources, increase efficiencies, reallocate funds, emphasise equity in service delivery, and adopt innovations. The task is two-fold: to address the acute crisis, and to transform health systems for this new era of global health. Both tasks have implications for how ext[illegible] partners provide support [illegible] financing, includ-

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WHO chief laments most disruptive cuts to global health funding 'in living memory'

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Rapid reductions in development assistance for health across the globe
call for strengthened partnerships and collaboration

Resolution WHA 67:20 recognized the importance of strong regulatory systems to a well-functioning healthcare system and the attainment of UHC and health-related SDGs

WHO provides technical support to Member States in regulatory systems strengthening for effective and efficient oversight of medical products

- capacity building consistent with good regulatory practices
- promoting global and regional regulatory harmonization, convergence, networking, working sharing and reliance

Improved access to quality assured, safe and effective medical products

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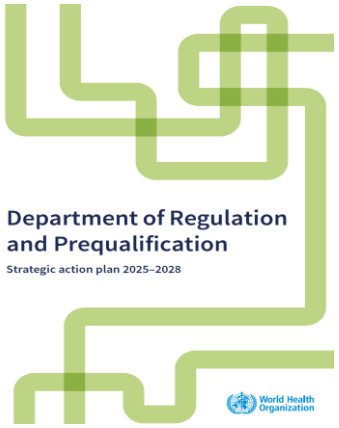
WHO Strategic Objectives: 2025-2028

Striving to advance in health equity & resilience through promoting, providing & protecting health & wellbeing

Strategic objectives of WHO's 14th GPW: 2025-2028

Strategic Action Plan for Dept Regulation and Prequalification (2025-2028)

To support Member States in strengthening robust, resilient & reliable regulatory systems through tailored approaches that ensure the quality, safety, effectiveness and accessibility of health products reaching all populations in need for universal health coverage and emergencies response



Strategic priorities

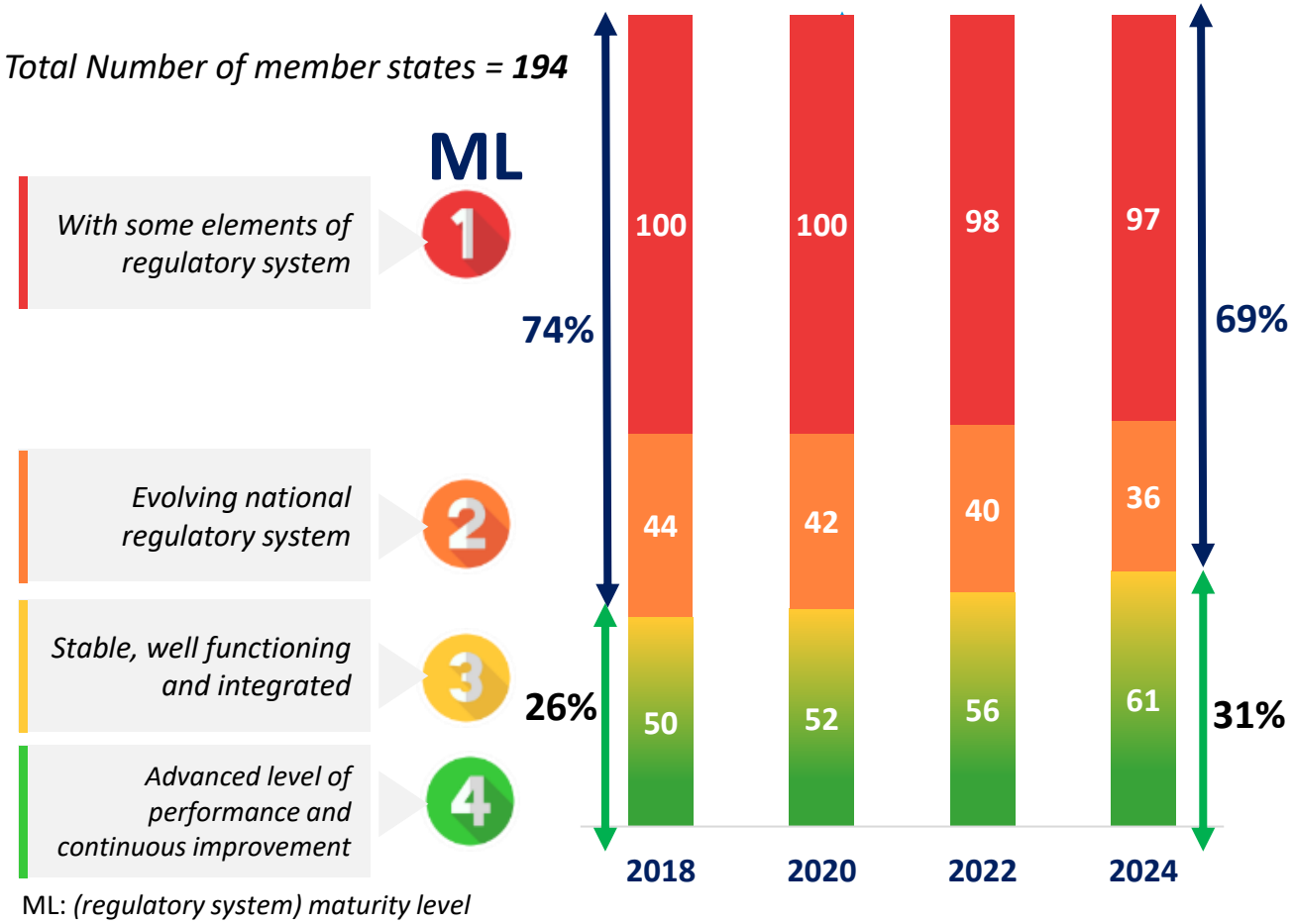
1. Strengthen country and regional regulatory systems in line with the drive towards UHC
2. Increase regulatory preparedness for public health emergencies
3. Strengthen and expand WHO PQ and product risk assessment processes
4. Increase the scope and impact of WHO's regulatory support activities
5. Optimize operational and accountability processes for greater country impact

RPQ Strategic Action Plan 2025-2028

World Health Organization

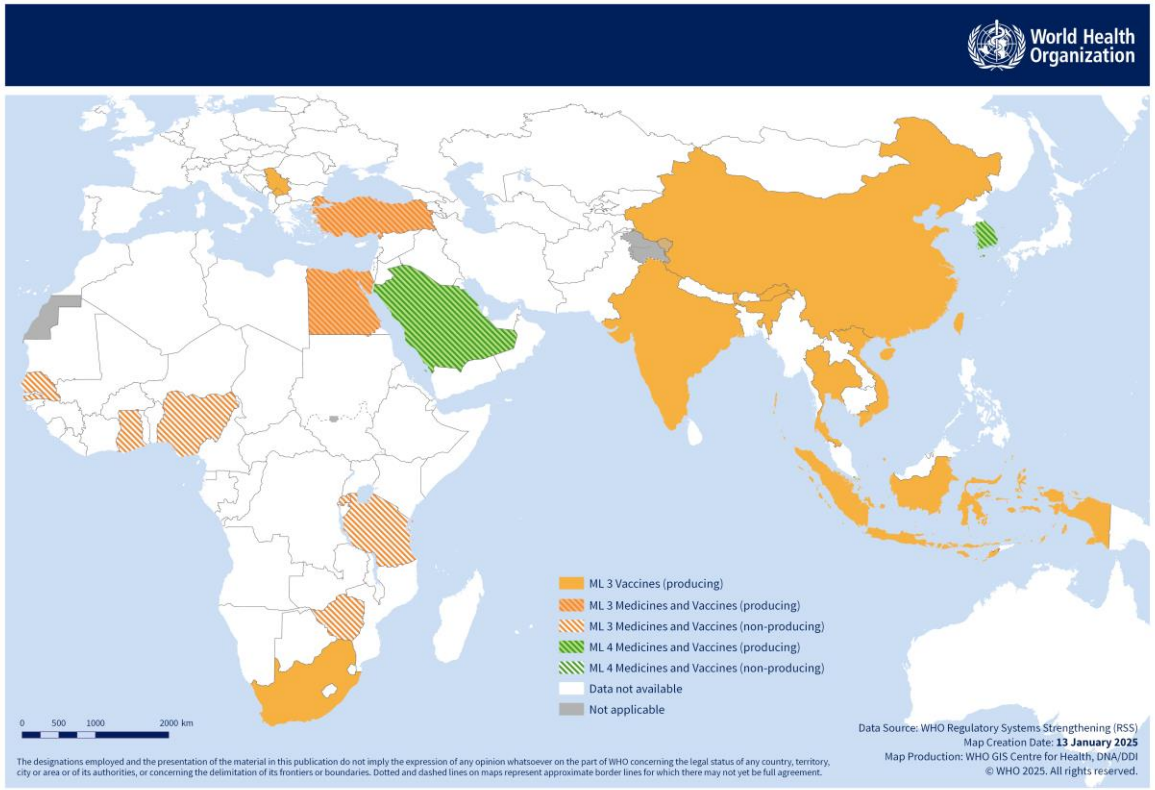
Global status of national regulatory systems

(includes WLAs & transitional WLAs for medicines and vaccines as of August 2025)



ML: *(regulatory system) maturity level*

NRAs benchmarked as ML3/ML4 using GBT



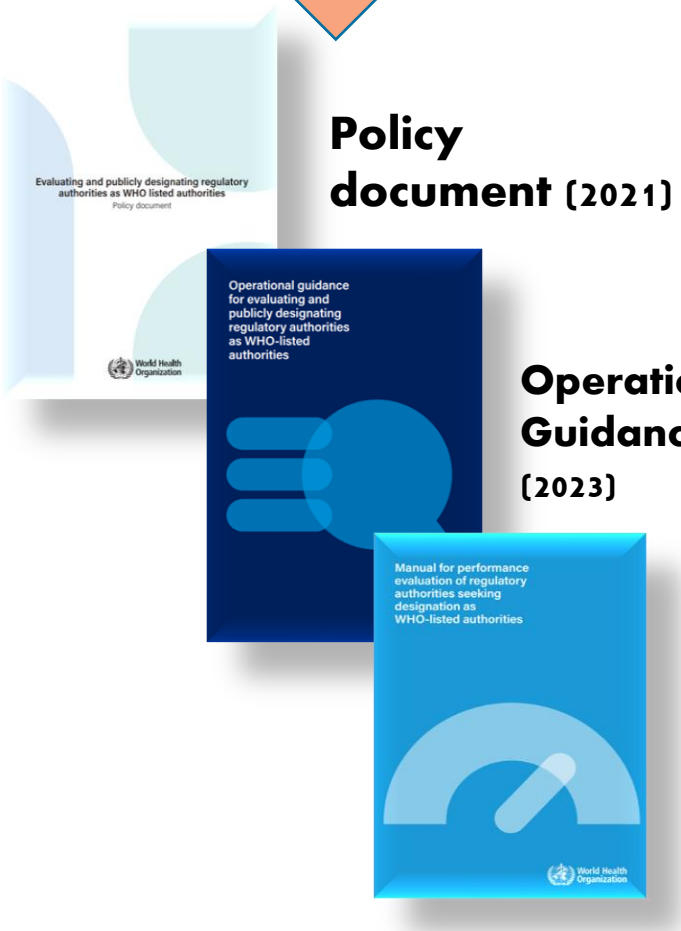
- **61 WHO member states (31%) have well-functioning regulatory systems**
  - ✓ **11 more NRAs achieved ML 3 or ML 4 since 2018 (22% growth)**
- **133 member states (69%) with NRAs still at ML 1 & ML 2**

- ***GBT:*** *Global Benchmarking Tool*
- ***NRA:*** *National Regulatory Authority*
- ***WLA:*** *WHO Listed Authority*

Source: WHO RSS database, August 2025

WHO Listed Authorities (WLAs)

WLA Framework



Policy document (2021)

Operational Guidance (2023)

Manual for Performance Evaluation (2023)

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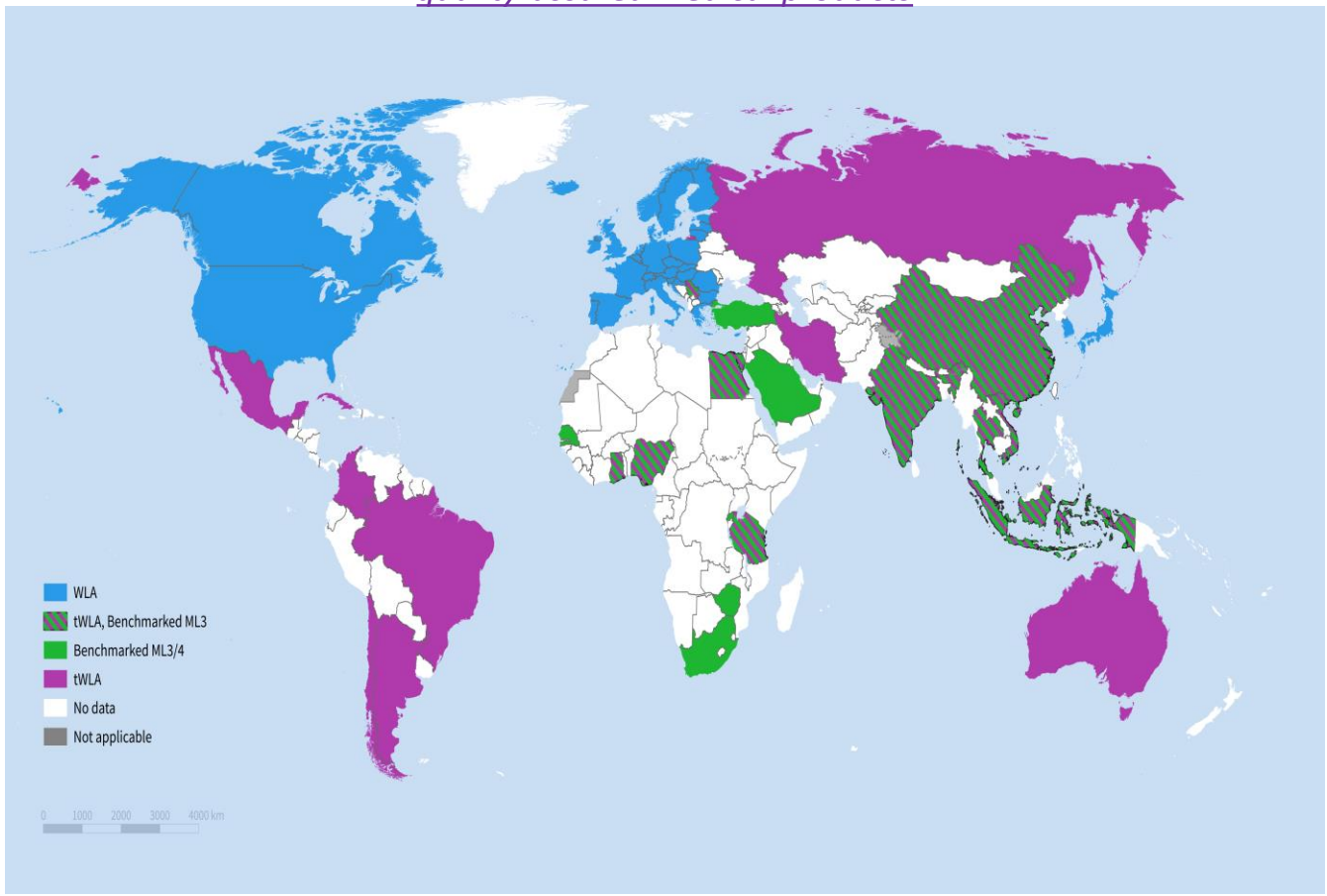
Global status of National regulatory systems (2016 – Aug 2025)

39 WLAs with the latest listing of Health Canada, MHLW/PMDA of Japan, and MHRA of the UK

WHO designates new WHO-Listed Authorities, strengthening global access to quality-assured medical products



Source: WHO Regulatory System Strengthening database, August 2025

List of WHO Listed Authorities (last update: July 2025)

List of transitional WLAs (last update: July 2025)

Reliance is “smart regulation” and the 21st century regulatory tool

The Why?

More efficient use of global regulatory resources
Better global oversight

The How?

WHO Good Reliance Practices

Short eLearning Module – Main principles and examples of reliance
(Oct 2022)
https://whoacademy.org/coursewares/course-v1:WHOAcademy-Hosted+H0032EN+H0032EN?from=discovery&source=edX

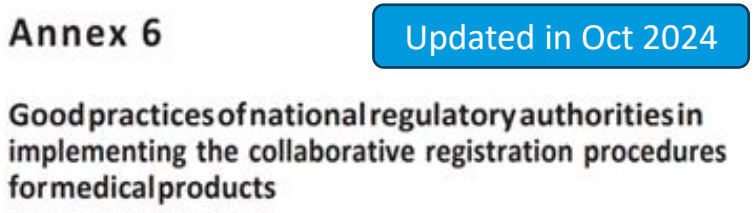

IPRP
International Pharmaceutical Regulatory Programme

IPRP Questions and Answers document[1] on Reliance
Version dated 30 September 2022

Table of Contents

International Pharmaceutical Regulators Programme - Q& A on Reliance
https://admin.iprp.global/sites/default/files/2022-11/IPRP_RelianceQ%26As_2022_0930.pdf

IPRP Good Reliance Practice Repository Current models and frameworks
(Oct 2024) - https://www.iprp.global/news/iprp-good-reliance-practices-repository-now-published


Annex 6

Good practices of national regulatory authorities in implementing the collaborative registration procedures for medical products

Updated in Oct 2024

Good Practices for the Collaborative Registration Procedure: Practical recommendations for CRP implementation but principles applicable to other reliance pathways (manual for reliance) – updated and adopted by the WHO Expert Committee in October 2024

WHO Global Benchmarking Tool & WHO Listed Authorities framework

Technical support to countries for reliance implementation workshops, meetings, review of regulations and guidelines

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Conclusions

- **Partnership and collaboration through Coalition of Interested Parties (CIP)**
  - ❖**WHO Network of Partners in regulatory systems strengthening**
    - ✓promotes a unified, strategic and coordinated approach to national and regional regulatory strengthening
    - ✓avoids duplication, burdening countries and enhancing complementarity

- **EDQM scientific expertise, resources, technical support and collaboration with WHO**
  - ✓ setting global norms and standards for quality assured medical products
  - ✓strengthening regulatory systems, incl. addressing substandard and falsified medical products
  - ✓using CEP Procedure to promote trust and advance the concept of reliance

World Health Organization

Regulation and Safety Unit