


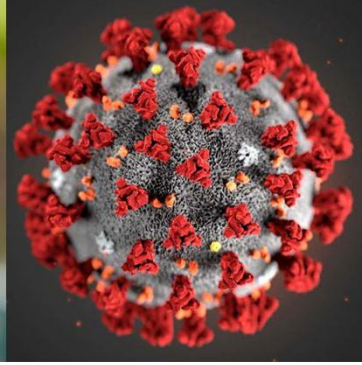

Animal Testing Replacement for Vaccines

A One Health View: Global Outlook and Future Strategy

World Health Organization

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Regulatory Systems Strengthening (RSS/REG/RPQ)




Session. How future proof regulations could support vaccines' release paradigm's change: Addressing reliance

Date: 4 December 2025

Venue: Hotel Westin Grande Sukhumvit, Bangkok, THAILAND

WHO guidance addressing reliance/recognition

- TRS 1033 - Annex 10: Good reliance practices in the regulation of medical products: high level principles and considerations
- TRS 1033 - Annex 11: Good regulatory practices in the regulation of medical products
- TRS 993 – Annex 4: Guidelines on procedures and data requirements for changes to approved vaccines
- TRS 978 – Annex 2: Guidelines for Independent Lot Release of Vaccines by Regulatory Authorities

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 facilitates timely access to safe, effective, quality-assured medical products (see section 3. Scope) and can support regulatory preparedness and response, particularly during public health emergencies.

Good reliance practices (GRelP) are anchored in overall good regulatory practices (GRP) (*1*), which provide a means for establishing sound, affordable, effective regulation of medical products as an important part of health system strengthening. If implemented effectively, GRP can result in consistent regulatory processes, sound regulatory decision-making, increased efficiency of regulatory systems and better public health outcomes. NRAs are encouraged to adopt GRP to ensure that they are using the most efficient regulatory processes possible.

WHO is establishing and implementing a framework for evaluating regulatory authorities and designating those that meet the requirements as "WHO-listed authorities" (WLA) (*4*). Using the WHO Global Benchmarking Tool (*5*) and performance evaluation, WHO will assess the maturity and performance of a regulatory authority to determine whether it meets the requirements of a WLA and thereby provide a globally recognized, evidence-based, transparent system that can be used by NRAs as a basis for selecting reference regulatory authorities to practise reliance. A list of reference regulatory authorities is available on the WHO website (*6*).

In September 2019, WHO held a consultation to solicit input on the nature, structure and overall content of a document outlining GRelP. The meeting concluded that the concept note and recommendations on regulatory reliance principles of the Pan American Health Organization (PAHO) and the Pan American Network for Drug Regulatory Harmonization (*7*) should be used as a basis for the WHO document on GRelP. The high-level document would be complemented by a repository of case studies, practice guides and examples of practical application of GRelP.

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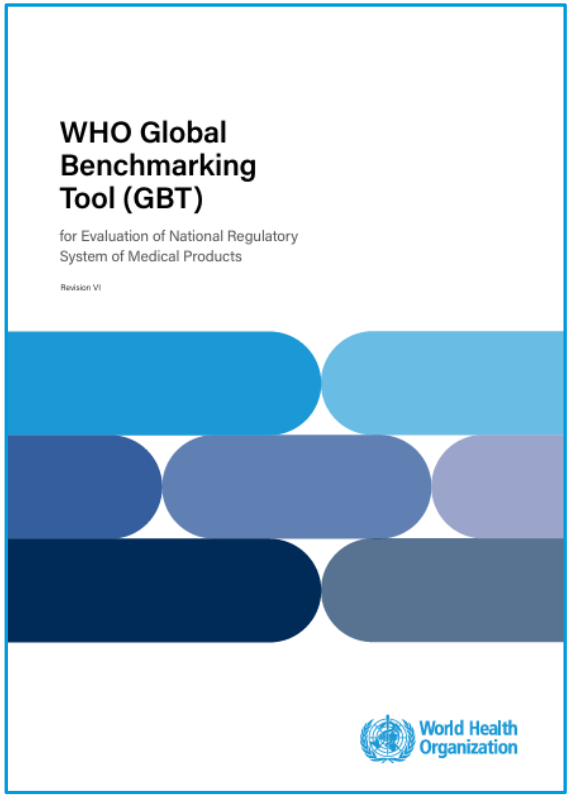
WHO Global Benchmarking Tool

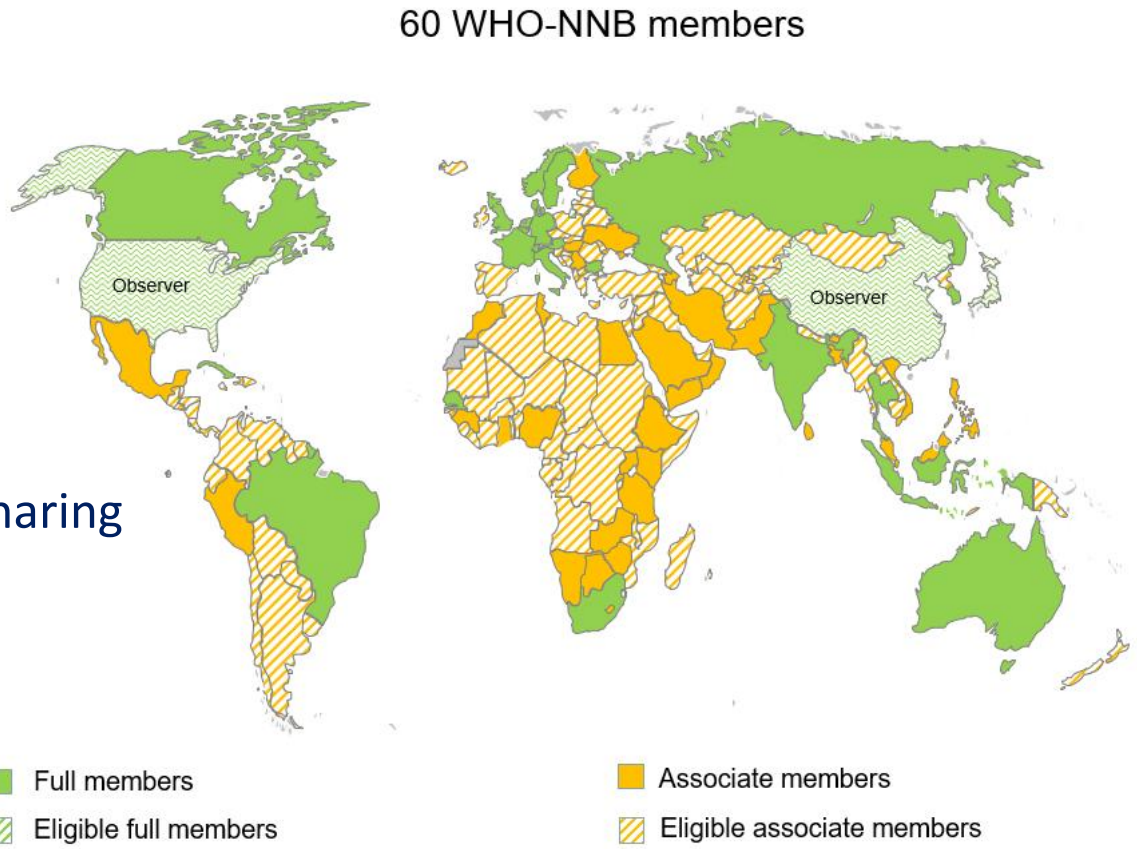
WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems of medicines and vaccines.

- *RS03.04: Documented policies, procedures and mechanisms, including written criteria, are established for recognition and reliance on decisions of other NRAs (if applicable)*
- ML3 status: signals a functional NRA others can rely on.



In practice

- WHO National Control Laboratory Network for Biologicals (WHO-NNB)
- WHO-NNB information sharing platform



Avoiding redundant testing of PQ-ed vaccines

World Health Organization

To make lot-release data and information available in importing countries, and thus avoid redundant retesting, a 2-step procedure is proposed:

- Manufacturer authorization: Permission for NCLs to share relevant LR data with WHO and Network members
- NCL agreement: Consent from the respective NCLs to share the data through the WHO-NNB platform

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WORKING TOGETHER

Department of Regulation and Prequalification, WHO