Regulatory strengthening in Latin America in times of COVID-19 and its impact on Self-Care

# WHO Good Reliance Practices guidelines to support regulatory decision making

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World Health Organization

# Access to essential medicines - part of the right to health

**The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition“**

**WHO Constitution, Chapter II – Functions, Article 2 (c)**

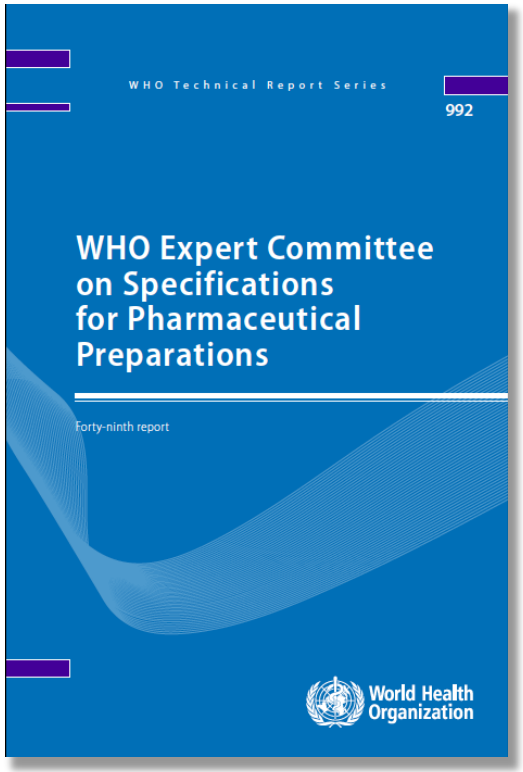
The Constitution was adopted by the International Health Conference held in New York from 19 June to 22 July 1946, signed on 22 July 1946 by the representatives of 61 States and entered into force on 7 April 1948.

# Access to medical products – global challenge


- Good health is impossible without access to medical products;
- Universal Health Coverage depends on the availability of quality-assured affordable health technologies in sufficient quantities;
- An estimated **two billion people have no access to essential medicines**, effectively shutting them off from the benefits of advances in modern science and medicine.
- Reasons for limited/insufficient access are numerous – including inadequate regulatory capacity and lack of collaboration and work sharing in medicines regulatory area between countries.

# Globalization in medical products regulation (1)

- All medical products should be used in the countries **only after approval by the national or regional regulatory authority - in line with current international standards** (WHA Resolutions: WHA 67.20 (2014); WHA 67.21 (2014); WHA63.12 (2010)**;**
- There is no clear vision or policy about HOW to set up regulatory systems in times when it is unrealistic to manage all functions in one national setting for most regulators – **globalization of regulatory science**;
- New products are likely more complex and sophisticated – demanding advanced health systems and "quality use“.



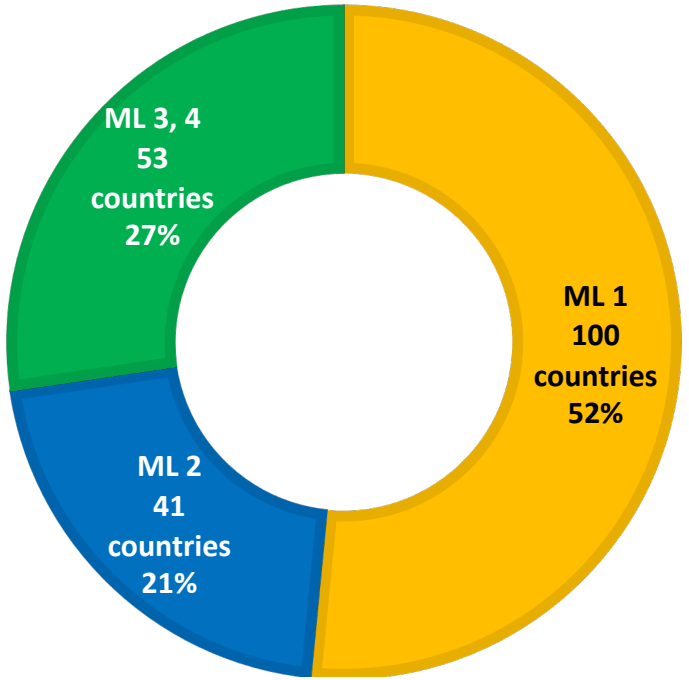
# Globalization in medical products regulation (2)

- Ability/need to assess and inspect all products coming to the markets:
  - Does repetitive assessments and inspections give any added value?
- How to build confidence in scientific assessments/ inspections carried out by other regulators?
- Are new products equally fit for all types of health systems and health providers available?
- Benefit/risk assessment taking into consideration health systems in which product is to be launched?
- What exact competencies are needed for regulators – to perform key regulatory functions?

# Capacity to regulate medical products globally

- Less than 1/3 of NRAs globally have capacity to perform all regulatory functions;
- Regulatory capacity gap between different countries (low- and high-income) in terms of:
  - Human and financial resources;
  - Regulatory functions effectively performed;
  - Expertise available for fulfilling regulatory functions;
  - Availability of proper systematic training for regulators;
  - Applying quality management principles.

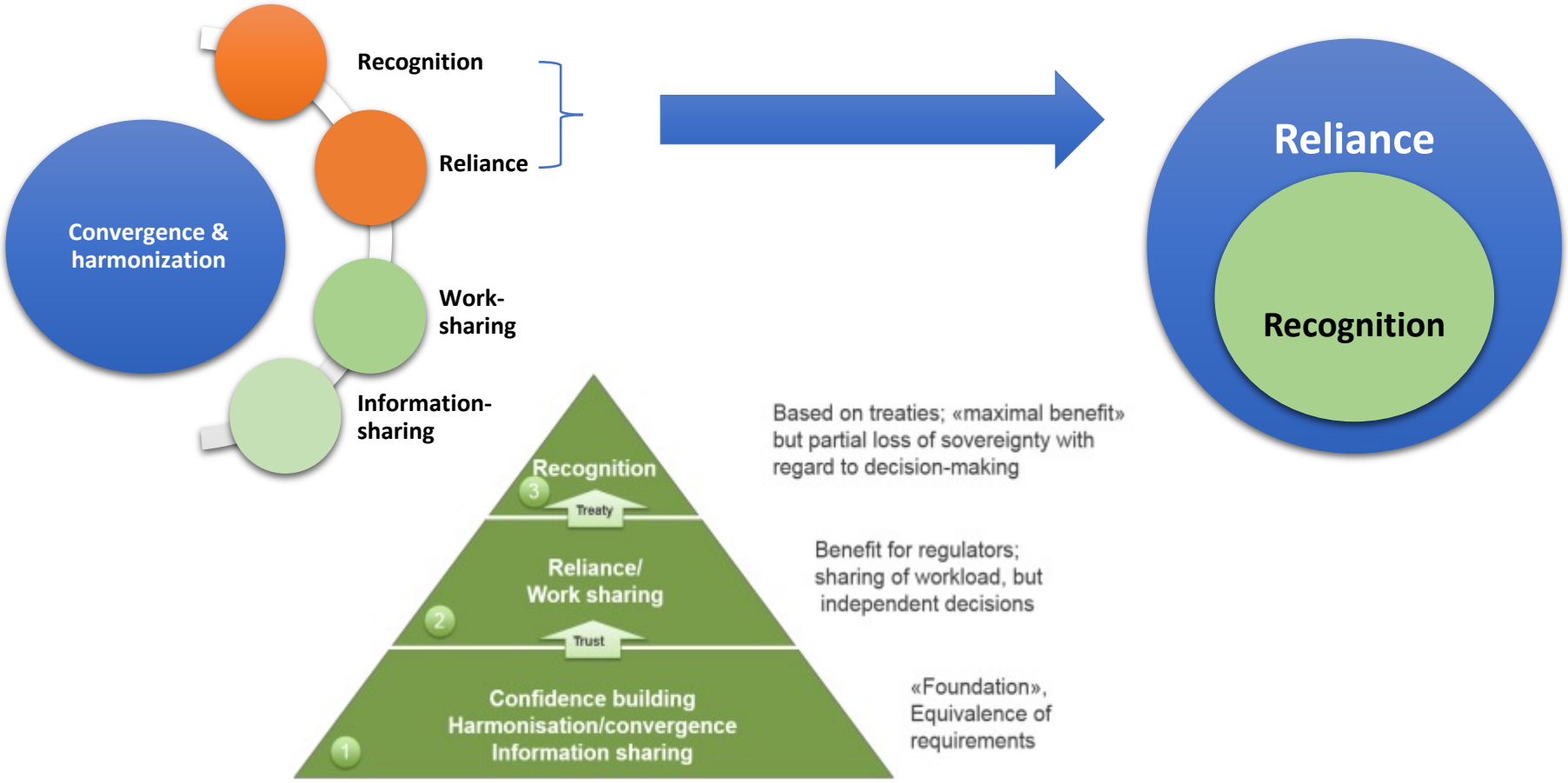
**194 WHO Member States:**



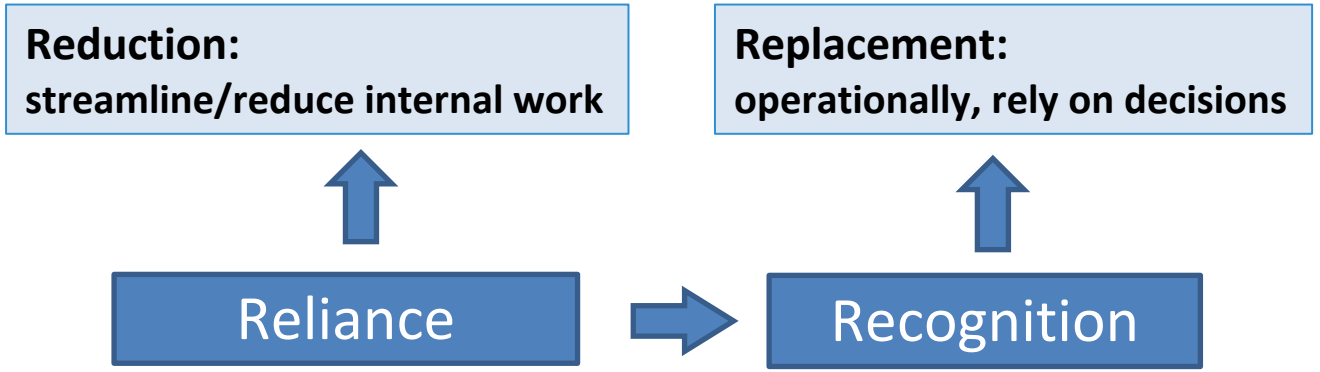
# WHO efforts to facilitate good quality decisions – based on reliance

- Promoting good governance and transparency in medical products sector – **Good Regulatory Practices** process;
- Promoting and facilitating the processes to build strong national regulatory systems as:
  - part of overall health systems strengthening – Global Benchmarking process;
  - as important contributor to achieving universal health coverage and able to address public health priorities;
- Supporting regulatory workforce development – Global Regulatory Curriculum;
- Promoting **reliance** through regulatory cooperation, convergence and harmonization;
- Promoting work sharing – based on **reliance** on the work of trusted regulatory authorities to inform national regulatory decision-making.

# Views on Regulatory Cooperation



# Reliance and Recognition




- Both reflect "taking account of'' the output of other agencies
- Increasing prevalence/necessity, even with most mature/resourced agencies
- Prerequisite: regulatory system and functions that can then be the object of reliance or recognition
- Both may be unilateral or mutual
- Desirable to establish guiding principles for each
- Recognition usually requires specific regulatory authority
- Reliance usually operates within existing regulatory framework
- **NB: sovereignty maintained in both cases**

# Principles of Reliance to support national decision making

International cooperation is essential to ensure the safety, quality and efficacy/performance of locally used medical products. No regulatory authorities even the best-resourced one can do it alone.

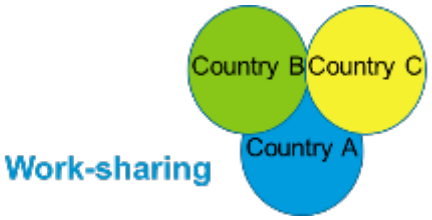
Make best use of available resources and expertise, avoid duplication and concentrate regulatory efforts and resources where most needed.
Promote a more efficient approach to regulatory oversight, thereby improving access to quality-assured, effective and safe medical products over the entire life-cycle.

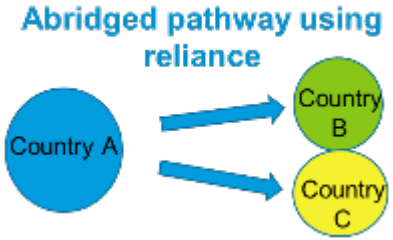
RELIANCE - the act whereby the regulatory authority in one jurisdiction **takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information in reaching its own decision**.

The relying authority remains independent, responsible and accountable regarding the decisions taken, even when it relies on the decisions, assessments and information of others.

# Options to facilitate good quality regulatory decisions – reliance in the focus


Standard processes

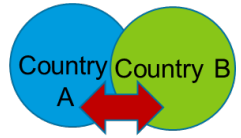



Work-sharing, including joint activities
Abridged pathways using reliance

Recognition


Unilateral




Mutual recognition

**Independent decisions**
based on its own reviews and/or inspections

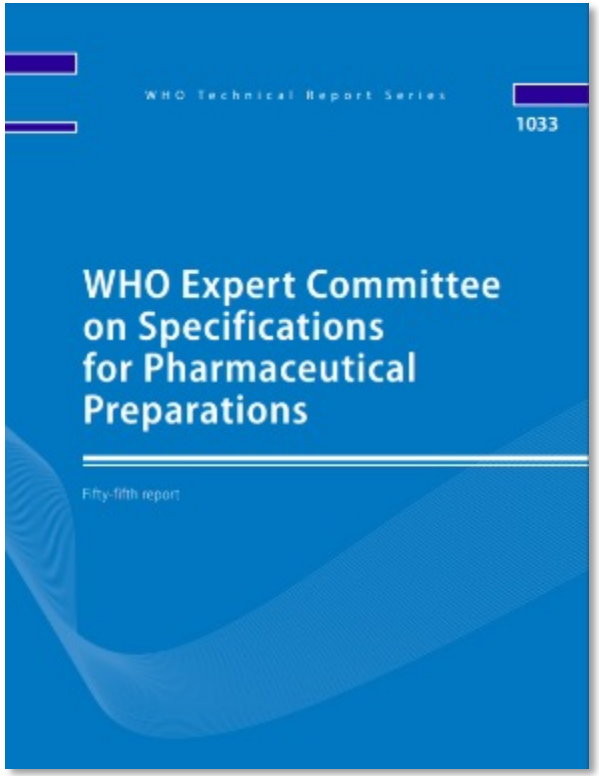
**Leveraging regulatory work**
Performed by other competent and trusted authorities to reduce the workload

**Unilateral or mutual recognition**
based on treaties or equivalent

Building trust between NRAs, increasing reliance and efficiency

# WHO Good Reliance Practices - Scope

- Covers reliance activities in the field of **regulation of medical products** (i.e., medicines, vaccines, blood and blood products and medical devices including in vitro diagnostics)
- Addressing **all regulatory functions** as defined in the Global Benchmarking Tool (registration and marketing authorization, vigilance, market surveillance and control, licensing establishments, regulatory inspection, laboratory testing, clinical trials oversight, and NRA lot release) - spanning the full life cycle of a medical product.




The high-level document will be complemented in a second step by a repository of case studies, practice guides and examples of practical applications of GReIP

https://apps.who.int/iris/bitstream/handle/10665/340323/9789240020900-eng.pdf

# Reliance is “implanted” in facilitated regulatory pathways

**MAIN PRINCIPLES:**

- **Sharing information / expertise** (assessment, inspection and testing results or expertise) that serve as basis for national decisions – avoiding duplication.
- **Voluntary participation** – reference authorities, participating authorities and manufacturers/sponsors

## WHO PQ collaborative registration procedure

**Vaccines: 2004**

- **Medicines: Started in 2012**
- **Diagnostics: Pilot 2019**
- **Vector control: Pilot 2020**

**CRP-lite

## “SRA” collaborative registration procedure

**Initiated in 2015**

- **European Medicines Agency (EMA)**
- **UK Medicines and Healthcare Products Regulatory Agency (MHRA)**
- **20 African NRAs**

## Regional networks

**African Medicines Regulatory Harmonization Initiative (AMRH)**

**ASEAN SIAHR Project**

# Facilitated national decision making based on reliance

- Regulators worldwide can benefit from already conducted scientific assessments and inspections to support national registrations, if:
  - Have access to regulatory expertise from trusted party (complete assessment and inspection reports);
  - Have the same product;
  - Have the same essential technical data;
  - Understand validity of B/R data for local environment;
- **Important to mention that:**
  - National legislation and sovereignty are not affected;
  - Confidentiality of commercially sensitive information is respected;
  - Regulatory follow-ups are properly managed.

# Collaborative Registration Procedure: 44 Participating NRAs, plus 1 Regional Economic Community

As at 30 Nov 2020

Armenia
Azerbaijan
Belarus
Botswana
Burkina Faso
Bhutan
Burundi
Cameroon
*Caribbean Community (CARICOM)
Comoros
Cote d'Ivoire
Dem. Rep. Congo
Eritrea
Ethiopia
Georgia
Ghana
Kazakhstan
Kenya
Kyrgyzstan
Lao PDR
Madagascar
Malaysia
Malawi
Mali
Mauritania
Mozambique
Namibia
Nigeria
Pakistan
Philippines
Rwanda
Senegal
Sierra Leone
South Africa
Sri Lanka
Sudan
Tanzania
Thailand
Togo
Uganda
Ukraine
Uzbekistan
Zambia
Zanzibar
Zimbabwe

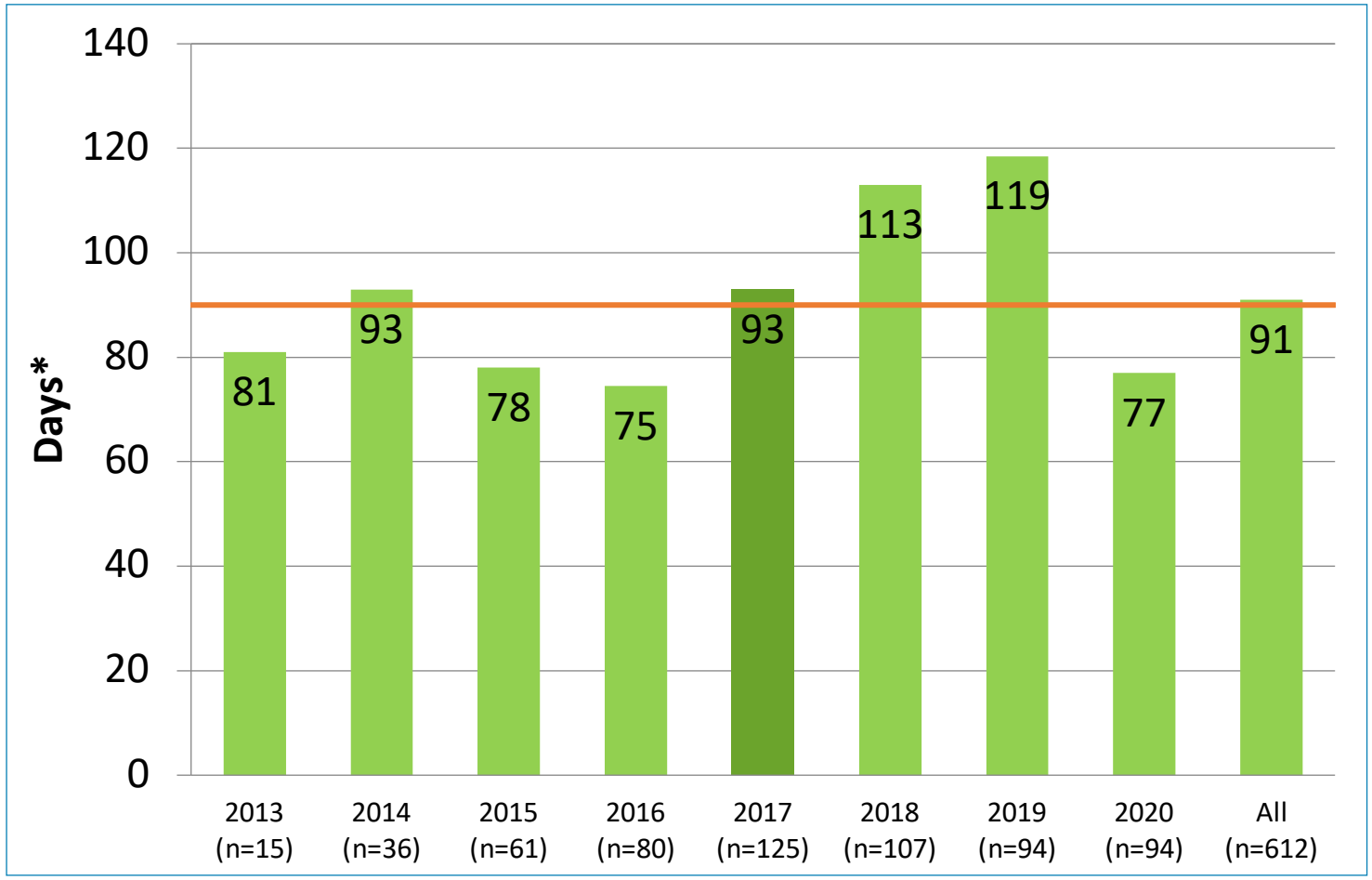
* CARICOM
Member States: Antigua and Barbuda, Bahamas, Belize, Dominica, Grenada, Haiti, Jamaica, Montserrat, Saint Lucia, St. Kitts and Nevis, St Vincent and the Grenadines, Suriname and Trinidad and Tobago
Associate Member States: Anguilla, Bermuda, British Virgin Islands, Cayman Islands and Turks and Caicos Islands

# Collaborative Registration Procedure: median time to registration

**Total registrations: 612**
**As at 30 Nov 2020**

**90 days TARGET**

*Including regulatory time and applicant time



# Summary/conclusions

- Not a single regulator anymore can fulfil all regulatory work alone and independently from other regulators;
- The future of medical products regulation is in convergence/ harmonization, collaboration and networking based on reliance and trust;
- Regulators are starting to operate as a functional network rather than individual players, and individual players focusing on where they can give the best added value;
- Regulatory networks have crucial role in improving efficiency of medical products regulation, ultimately improving access to most needed medical products for all.