

25th Anniversary of the Pan American Network for Drug Regulatory Harmonization (PANDRH)

Report of the Secretariat, balance and future perspectives

Objectives of the XI Conference

PAHO



PANDRH

Pan American Network
for Drug Regulatory
Harmonization

#UniversalHealth

What are we aiming for with regulatory harmonization?

Origin of PANDRH

Evolution

Main achievements

Challenges

Opportunities

Future

What are we aiming for with regulatory harmonization?

Effective regulation of health technologies promotes and protects public health by:



ensuring quality, safety,
and efficacy



facilitating the fight against
substandard and falsified
medical products



providing necessary information
to healthcare professionals
and patients



preventing access to technologies
from being hindered by
inefficient regulatory frameworks



The value of regulatory harmonization and convergence lies in minimizing obstacles to equitable and timely access to safe, effective, and quality medicines and other health technologies, a fundamental requisite for achieving universal health.

Origin of PANDRH



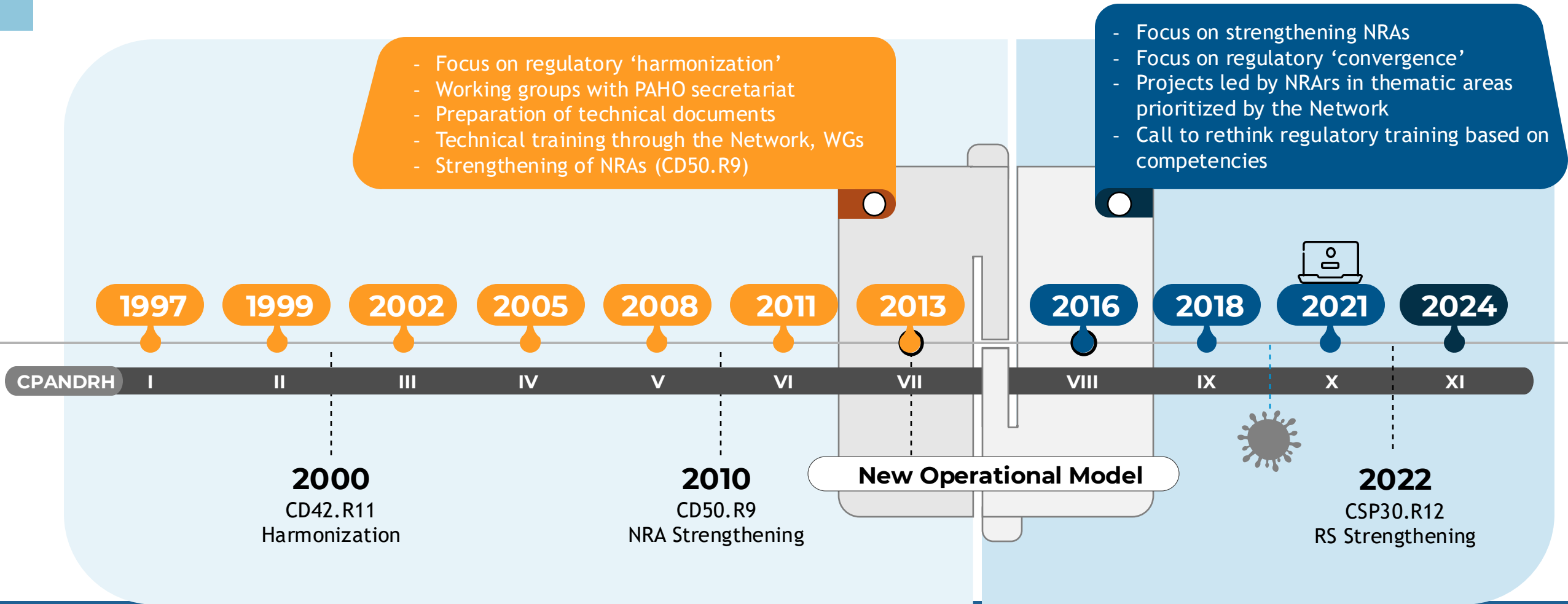
1997-1999

First Pan American Conferences on Drug Regulatory Harmonization

2000

The PANDRH Network is formalized through a resolution by the PAHO Member States

Evolution



- Focus on regulatory 'harmonization'
- Working groups with PAHO secretariat
- Preparation of technical documents
- Technical training through the Network, WGs
- Strengthening of NRAs (CD50.R9)

- Focus on strengthening NRAs
- Focus on regulatory 'convergence'
- Projects led by NRAs in thematic areas prioritized by the Network
- Call to rethink regulatory training based on competencies

Main achievements

Strengthening of regulatory systems for medicines



Conferences

Organization of 11 Pan American conferences on drug regulatory harmonization for the discussion and adoption of recommendations on priority topics of common interest for the Network members.



Multisectoral constructive dialogue

Promotion of a safe framework for constructive dialogue between various sectors, including regulators and the pharmaceutical industry.



Technical documents

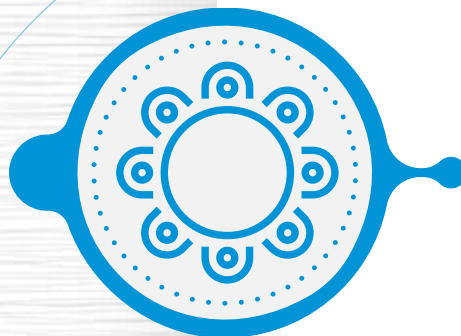
Development of multiple technical documents and guidelines for pharmaceutical regulation processes (harmonized proposals on priority and interest topics in pharmaceutical regulation) and adoption of technical standards at the national level in some jurisdictions

Main achievements



Technical projects

Dedicated to solving common problems for specific regulatory functions or health technologies, according to the priority areas defined by the Network.



Recognition of regional regulatory capacities

- Exchange and generation of knowledge about pharmaceutical regulation, including support for formulating criteria and decision-making.
- Inclusion of health technologies supervised by reference entities in regional acquisition processes to improve access for PAHO Member States.
- Exchange of experiences between NRAs and other Network members, contributing to the strengthening of countries' regulatory systems in the Region.



Network communication

Adoption of the Regional Platform on Access and Innovation for Health Technologies (PRAIS) as part of the operational model and governance of PANDRH.

Challenges



Changing regional context

Considering the challenges that countries faced during the COVID-19 pandemic, there is an urgent need to advance the strengthening of regulatory systems and harmonize regulatory standards before the next widespread health emergency, in order to minimize barriers to access to essential health technologies.



Multiple mechanisms of regional integration

With a range of strategic axes concerning pharmaceutical policy and regulation.



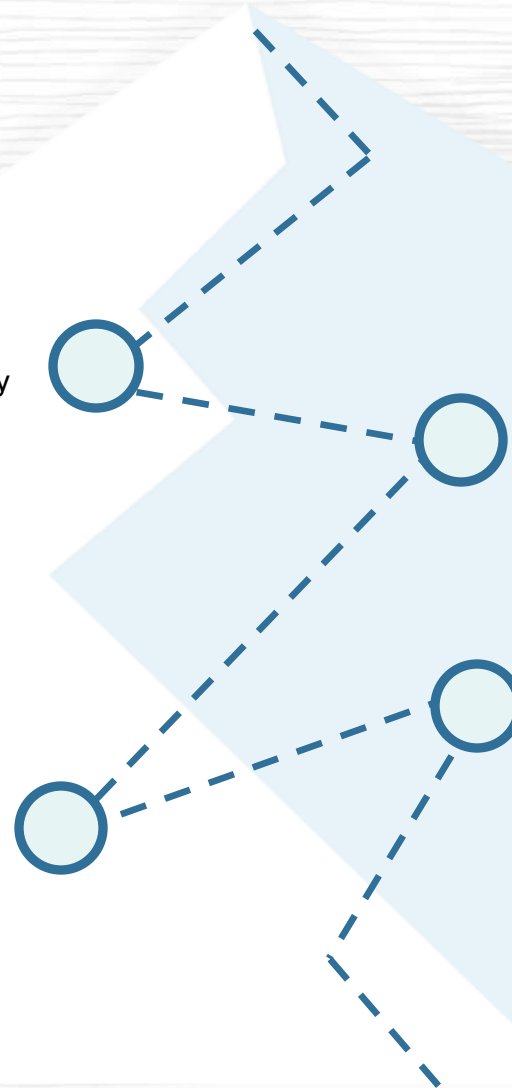
Asymmetries in the Region's regulatory capacities

Despite significant progress over the past decade, challenges and notable asymmetries remain in the Region's regulatory systems' ability to address new market demands and encompass the full range of health technologies relevant to health systems.



Multiple forums for harmonization and convergence

Increasing participation of countries from the Americas in global harmonization mechanisms.



Opportunities



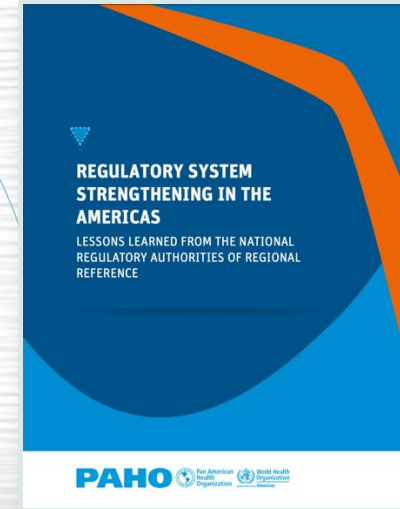
Synergies with other harmonization platforms

Deepen the ties and synergy of the PANDRH Network with the international harmonization mechanisms recommended by PAHO and WHO as sources of regulatory standards and best practices (e.g., ICH, IMDRF, PIC/s, among others)



Links with sub/regional integration initiatives

Strengthen the connections and communication of the PANDRH Network with key integration and sub/regional convergence initiatives, ensuring adequate representation of countries from various subregions in the discussions and decisions of the Network itself.



Regulatory convergence through the strengthening of efficient regulatory systems that promote timely and equitable access to quality medical products.

- Promote greater collaboration
- Respond to training priorities
- Foster innovation and production

Future

New strategic plan

Renew the plan, strategic objectives, and operating model of the Network with a view to strengthening it, in line with the recent mandates of the PAHO Member States and with the products identified as most needed for the Network.

Strengthening of the Network

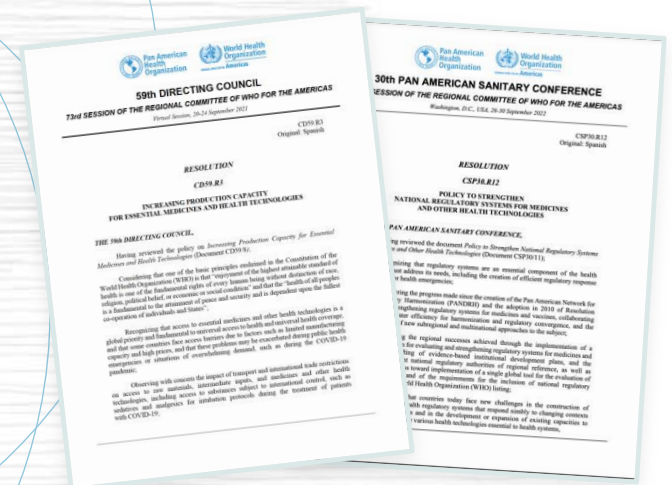
Strengthen the governance and secretariat of the Network to support technical management and strategic planning of activities, and constructive dialogue with the Network's various components.

Resource mobilization

Maximize existing resources and mobilize other resources and relevant actors to implement the Network's activity plan and biennial conferences, thus ensuring its technical and financial sustainability.

Greater visibility of the Network

Make the Network's work visible and integrate it with relevant audiences (regional and global forums and initiatives) to identify synergies and address issues of convergence and harmonization at the regional level.



How should the Network reposition itself to effectively address the current and future needs of the Region?

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