PANDRH Secretariat Report

10th Conference:

“The Regulatory Systems in the health agenda post COVID-19”

Extraordinary virtual session

6 December 2021

PAHO Pan American Health Organization

World Health Organization Americas

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OUTLINE


Topic 1 Regional advances since 9th PANDRH Conference
Topic 2 Objectives of the 10th PANDRH Conference
Topic 3 Announcements

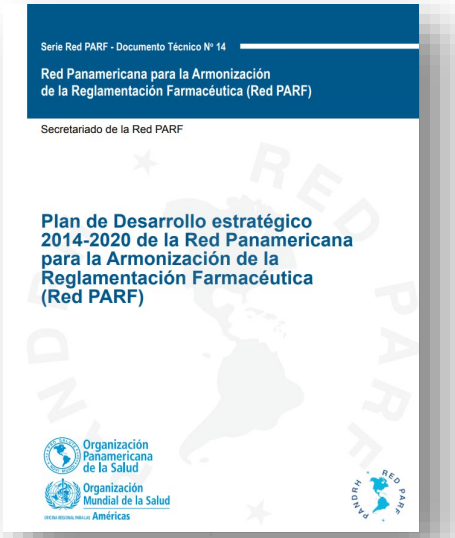
ADVANCES UNDER NEW PANDRH OPERATIONAL MODEL

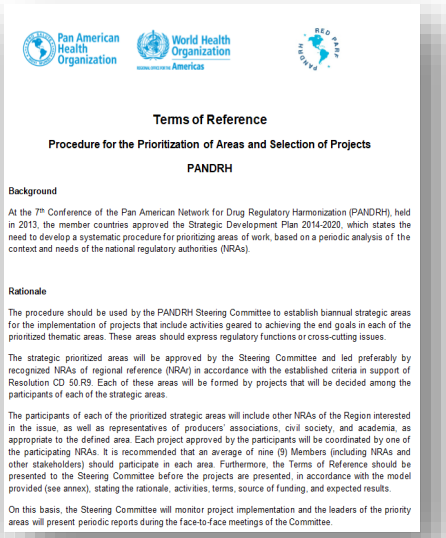
Milestones on relevant topics in the Region of the Americas: setting the ground

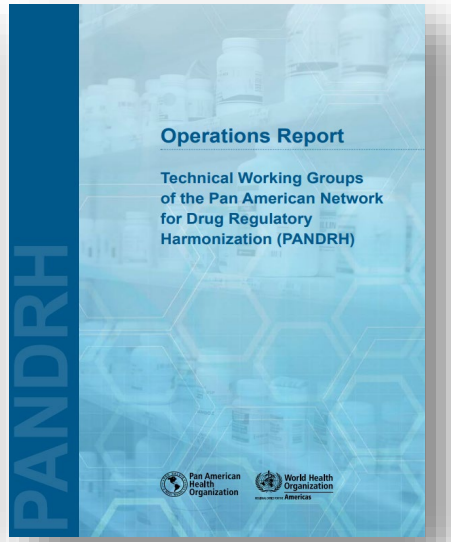
2013
7th Conference (CAN)

2016
8th Conference (MEX)

2018
9th Conference (SLV)







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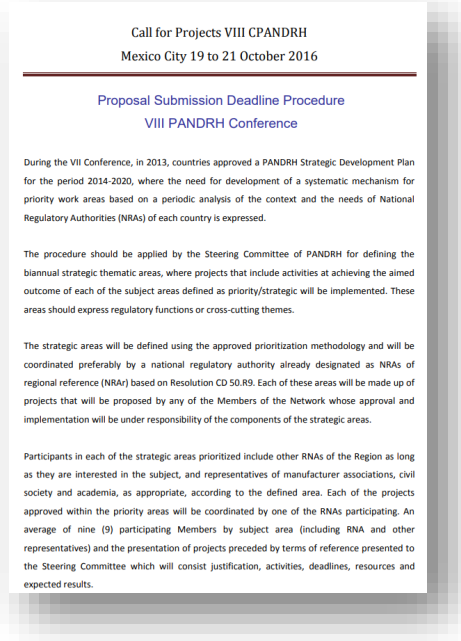

Call for Projects VIII CPANDRH
Mexico City 19 to 21 October 2016

Proposal Submission Deadline Procedure
VIII PANDRH Conference

During the VII Conference, in 2013, countries approved a PANDRH Strategic Development Plan for the period 2014-2020, where the need for development of a systematic mechanism for priority work areas based on a periodic analysis of the context and the needs of National Regulatory Authorities (NRAs) of each country is expressed.

The procedure should be applied by the Steering Committee of PANDRH for defining the biannual strategic thematic areas, where projects that include activities at achieving the aimed outcome of each of the subject areas defined as priority/strategic will be implemented. These areas should express regulatory functions or cross-cutting themes.

The strategic areas will be defined using the approved prioritization methodology and will be coordinated preferably by a national regulatory authority already designated as NRAs of regional reference (NRAr) based on Resolution CD 50.R9. Each of these areas will be made up of projects that will be proposed by any of the Members of the Network whose approval and implementation will be under responsibility of the components of the strategic areas.

Participants in each of the strategic areas prioritized include other RNAs of the Region as long as they are interested in the subject, and representatives of manufacturer associations, civil society and academia, as appropriate, according to the defined area. Each of the projects approved within the priority areas will be coordinated by one of the RNAs participating. An average of nine (9) participating Members by subject area (including RNA and other representatives) and the presentation of projects preceded by terms of reference presented to the Steering Committee which will consist justification, activities, deadlines, resources and expected results.

OPS | REVISTA PANAMERICANA DE SALUD PUBLICA

INICIO ACERCA DE NÚMEROS ESPE

Inicio / Números especiales / Fortalecimiento de los sistemas regulatorios de medicamentos

Fortalecimiento de los sistemas regulatorios de medicamentos

Health regulation is regarded as one of public health's basic functions. Effective regulation of medicines promotes and protects the public's health by guaranteeing medicines quality, safety, and efficacy; promoting the adequate manufacture, storage, and distribution of medicines; facilitating the fight against substandard, spurious, falsely-labeled, falsified, or counterfeit (SSFFC) medical products; providing the necessary information to health professionals and patients so they can use medicines rationally; and ensuring that access to medicines is not hindered by inefficient regulatory frameworks. Developing a national regulatory system is, hence, a critical component of a national health system.

ADVANCES UNDER NEW PANDRH OPERATIONAL MODEL

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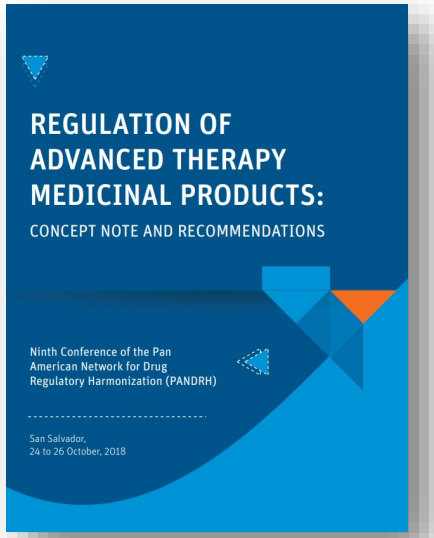
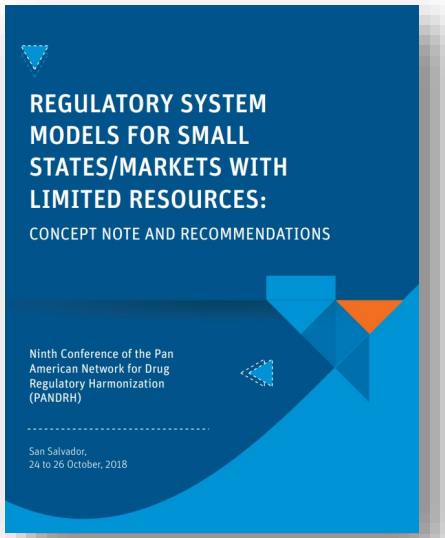
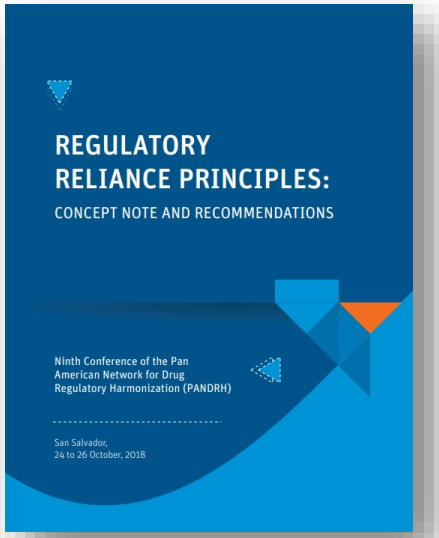






What has been the impact of these specific PANDRH products at the regional level?

Regional

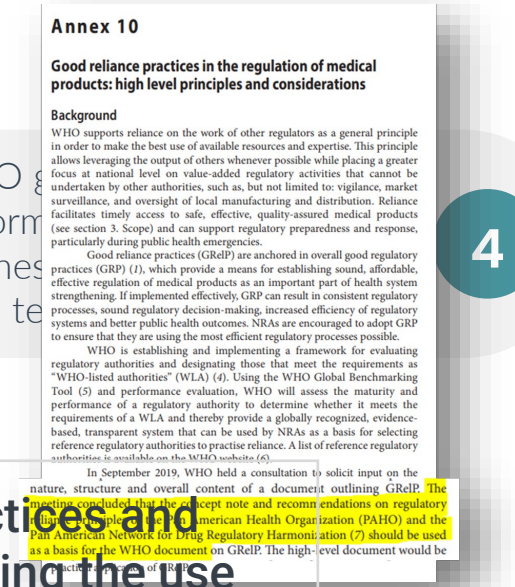
1 All NRAr have bilateral or multilateral arrangements with other countries to share information and cooperate

2 Reliance for Emergency Use Authorization of Medicines and Other Health Technologies in a Pandemic (e.g. COVID-19)

Global

WHO Good reliance practices in the regulation of medical products: High level principles and considerations 3

WHO g
public inform
19 vaccines
and te 4


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 developed by 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

Sub-regional

CRS uses these princi
recommendation

+210 recomm

REGULATORY SYSTEM STRENGTHENING IN THE AMERICAS

LESSONS LEARNED FROM THE NATIONAL REGULATORY AUTHORITIES OF REGIONAL REFERENCE

Landscaping...

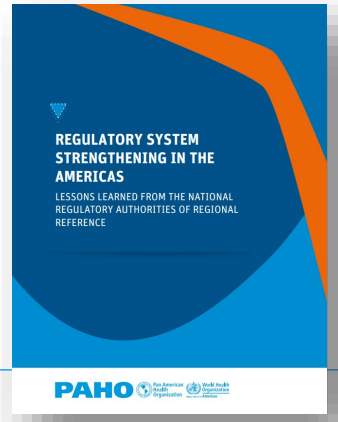
Captures best practices and efficiencies, including the use of reliance across the different regulatory functions studied

LESSONS LEARNED FROM THE NATIONAL REGULATORY AUTHORITIES OF REGIONAL REFERENCE

An overview of the report's findings

REGULATORY SYSTEMS STRENGTHENING IN THE AMERICAS:
Lessons learned from the National Regulatory Authorities of Regional Reference

1. National Regulatory Systems: An Overview
2. Market Outlook
3. Marketing Authorizations of Pharmaceutical Products
4. Marketing Authorizations of Similar Biotherapeutic Products
5. Good Manufacturing Practice Inspections
6. Pharmacovigilance and Post-market surveillance
7. Clinical Trials
8. Trade and Economic Integration Mechanisms
9. Postscript: Regulatory Emergency Response to the COVID-19 Pandemic in the Americas



Regulatory Systems Strengthening in the Americas

SCOPE

Focuses on the processes and practices of NRAr in Latin America and the industries and markets they oversee related to pharmaceutical regulation.

METHODOLOGY

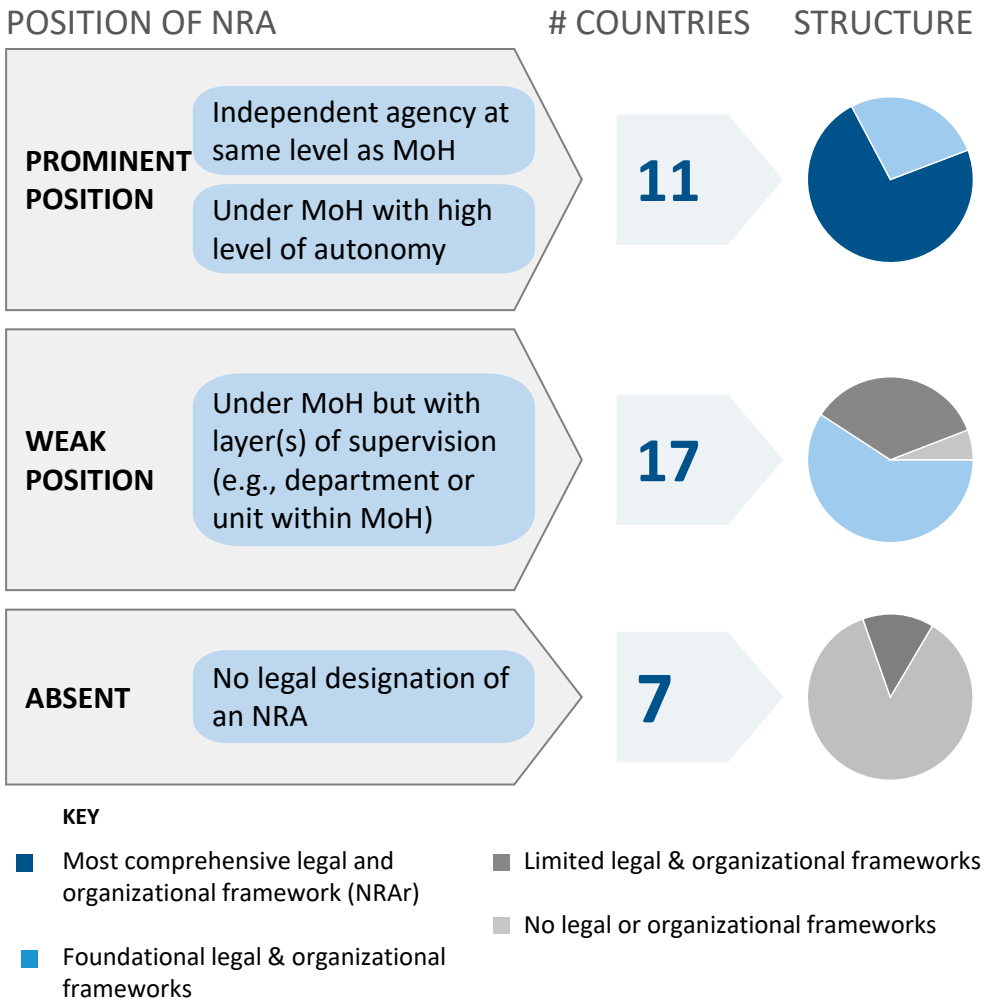
Literature reviews, analysis of PAHO data on regulatory assessment, desk reviews of NRA websites, and interviews with NRA officials and industry actors.

TARGET AUDIENCE

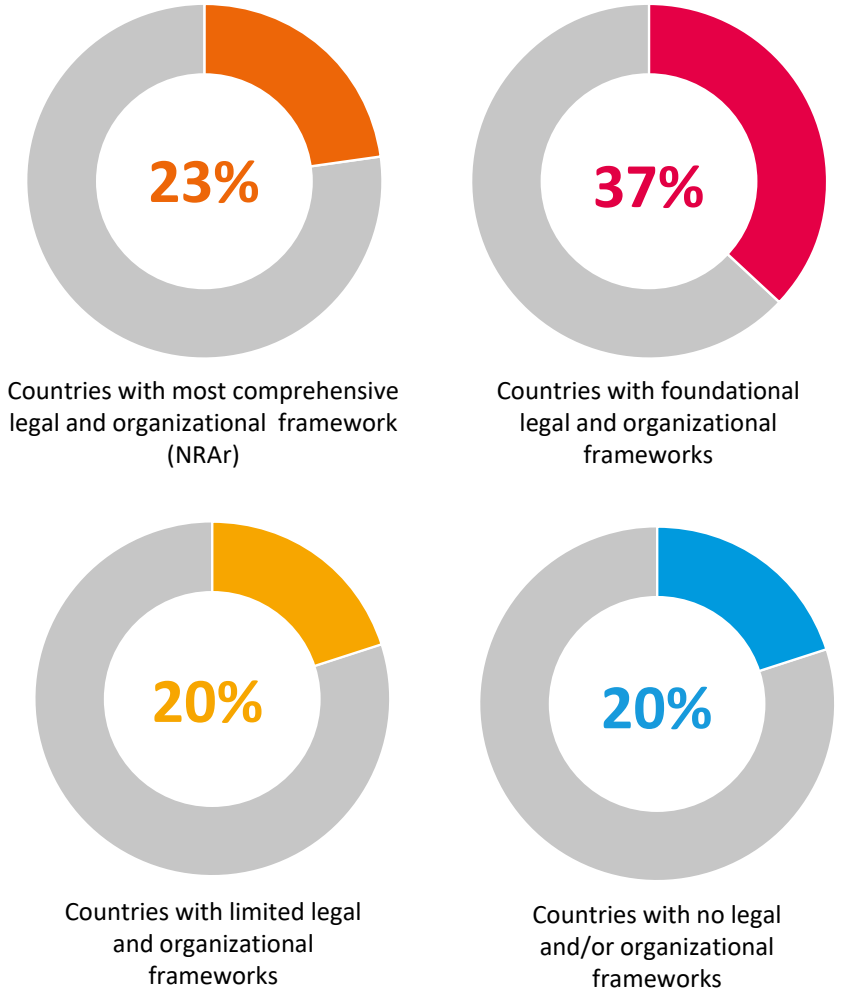
- NRAs
- Ministries of Health
- Ministries of Commerce & Finance
- Regional & Global Stakeholders including Industry

A SUMMARY OF THE REPORT'S FINDINGS

The position of NRAs within the health system's hierarchy in PAHO Member States



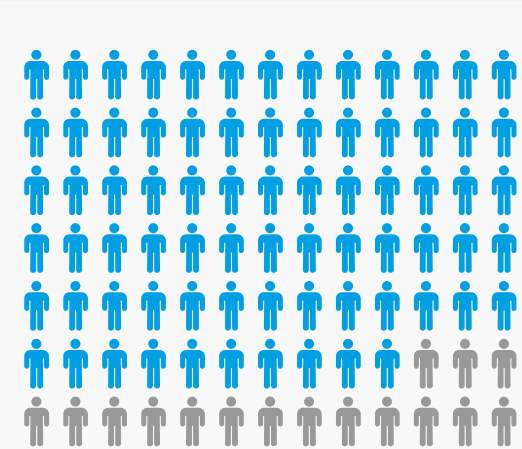
Legal and organizational structures for regulating medicines in PAHO Member States



A SUMMARY OF THE REPORT'S FINDINGS

- LA NRAr have relatively similar quality, safety, and efficacy requirements for the authorization of new chemical entities
- GMP inspection standards and approaches are relatively similar across NRAr
- All NRAr have similar legal provisions for PV and PMS using targeted or active PV to gain efficiencies in the detection and evaluation of medicines adverse reaction information, and their capacity to translate PV data into regulatoryaction is also increasing.
- All LA NRAr have a regulatory framework for clinical trials that is based on international guidelines, including approval by an ethics committee and good clinical practice inspections.

Together, the 8 reference authorities cover 82% of the population of the Americas but represent only 23% of the authorities in the region.



82% of the population of the Americas live in a country with a functional national regulatory system

Latin American NRAr participation in international harmonization initiatives (April,2021)

ICH

ICH promotes regulatory harmonization to improve resource efficiency.

Members:
- ANVISA

Observers:
- ANMAT
- CECMED
- COFEPRIS*
- INVIMA

ICMRA

PANDRH promotes collaboration to strengthen regulatory systems in the Americas.

Members:
- ANVISA
- COFEPRIS

Associate Members:
- ANMAT
- CECMED
- INVIMA

PANDRH

ICMRA promotes communication and information sharing to address common regulatory issues.

Members:
- All NRAs of the Americas

PIC/S

PIC/S promotes harmonized regulatory inspections and standards.

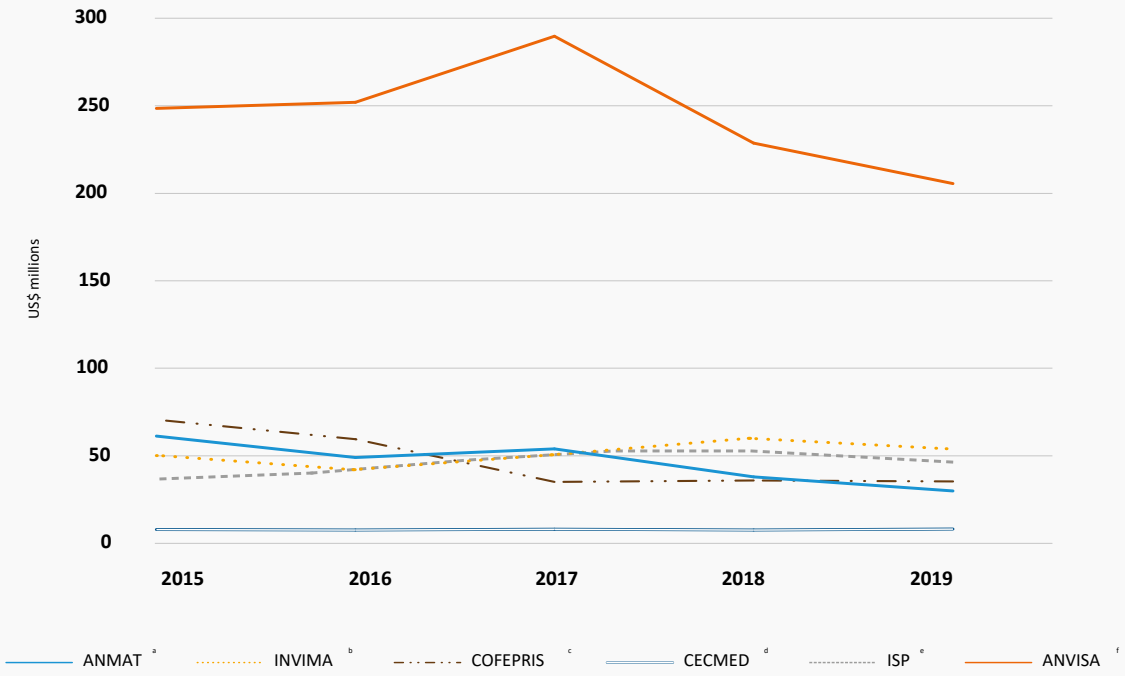
Members:
- ANMAT
- ANVISA
- COFEPRIS

*Currently COFEPRIS is an oficial member of ICH

PAHO Pan American Health Organization World Health Organization Americas

A SUMMARY OF THE REPORT'S FINDINGS

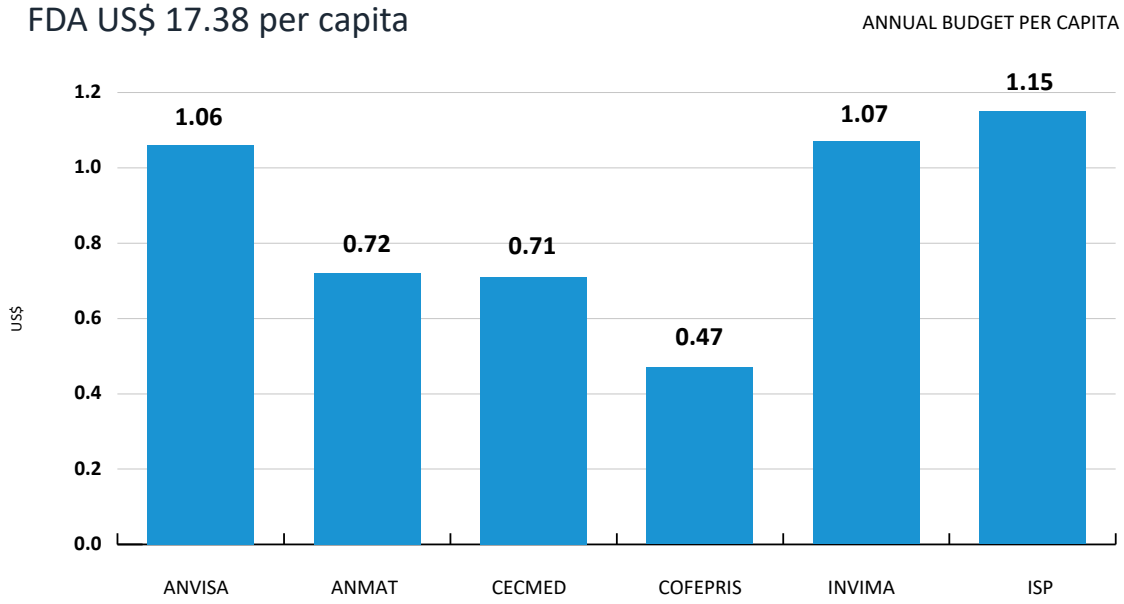
NRAr budgets over time (2015–2019)



The budgets for Latin American NRAr have remained relatively static over the past 5 years, but the pharmaceutical markets in most of these countries have increased in both value and volume

Annual budgets per capita for LAT NRAr in 2019

FDA US$ 17.38 per capita



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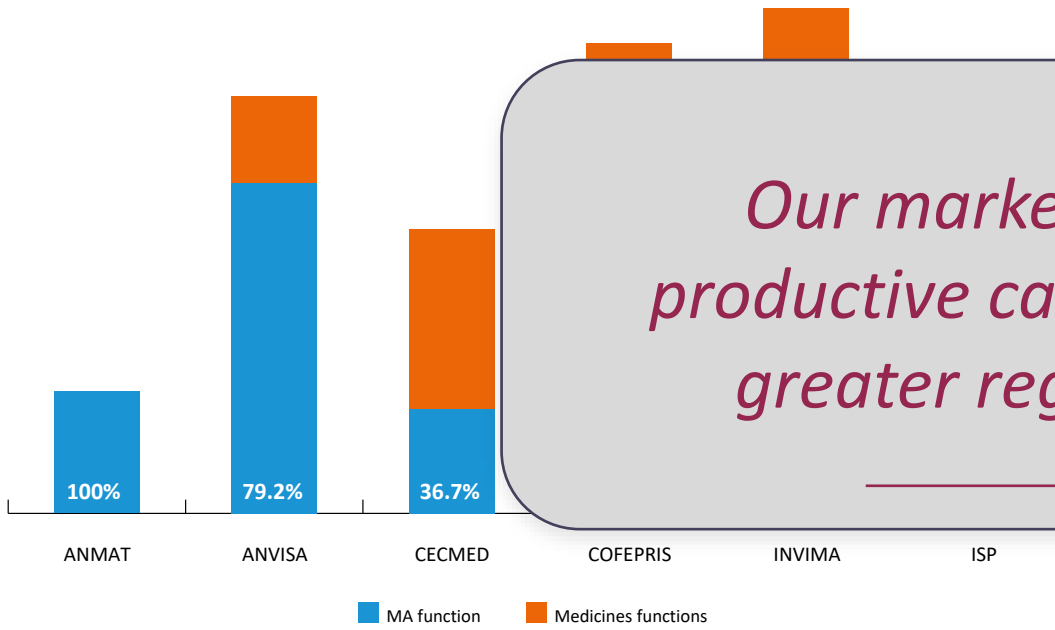
A SUMMARY OF THE REPORT'S FINDINGS

Number of staff devoted to marketing authorization in NRAr medicines units



Our markets have a growing productive capacity which requires greater regulatory capacity…

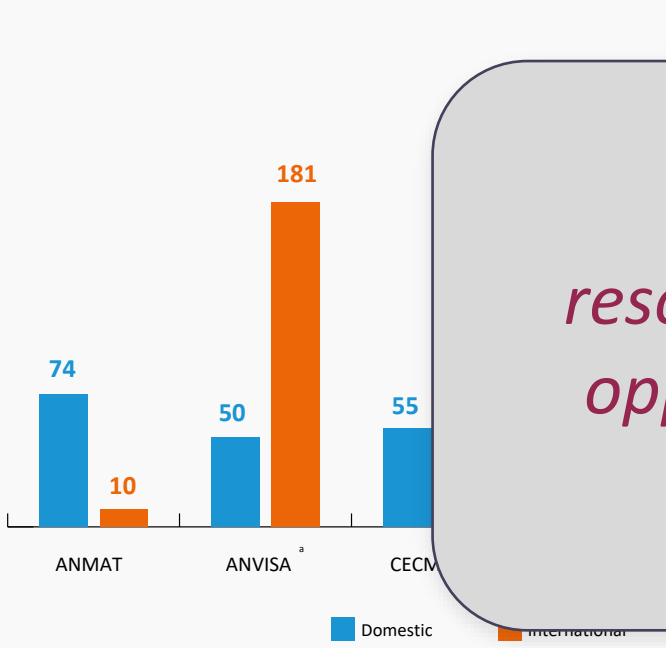
Post-market functions occupy a less relevant place than functions related to product authorization

Proportion of ADR reports to UMC by the Americas

Although around half of all the reports in VigiBase come from the Americas, Latin American countries represent less than 5%, and the proportion of those without NRAr is even less

A SUMMARY OF THE REPORT'S FINDINGS

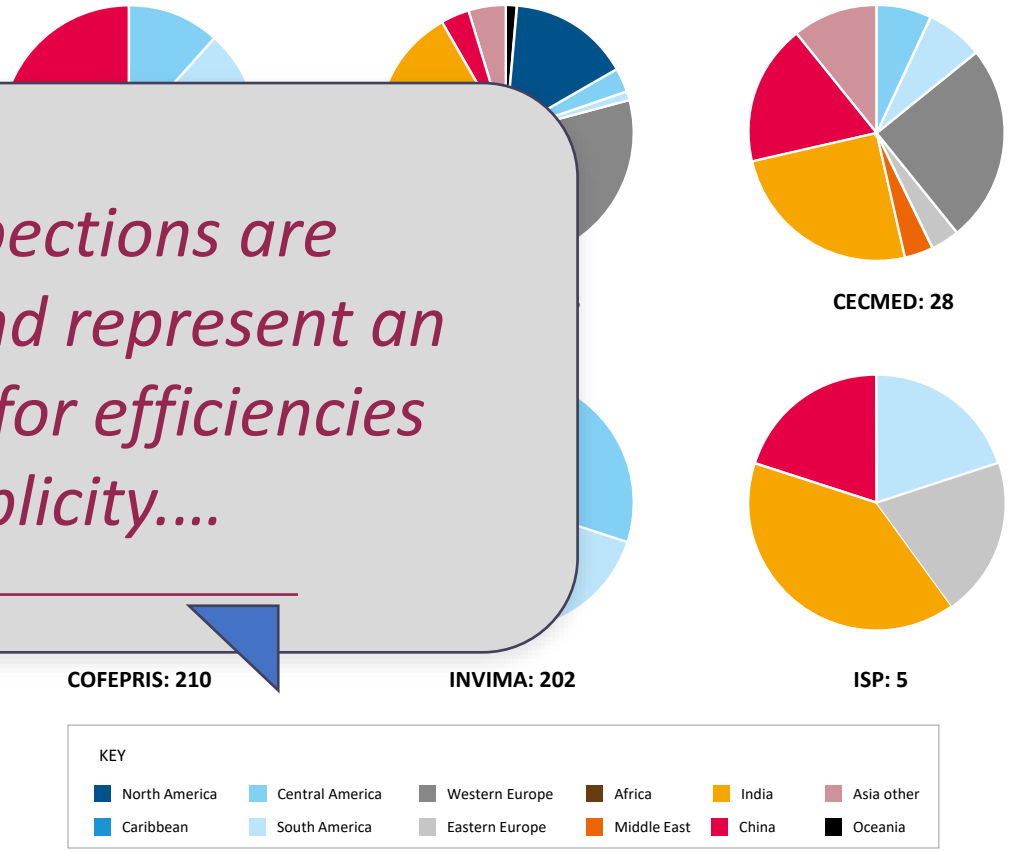
NRAr domestic and international inspections for medicines in 2018



International inspections are resource-intensive and represent an opportunity to seek for efficiencies and avoid duplicity....

Notes: These data do not include inspections carried out by state or municipal authorities. a) ANVISA's domestic inspection accounts only for GMP certification purposes and does not cover monitoring and investigational inspections.

Regional breakdown of NRAr international inspections for medicines, 2017–2019



ADVANCES IN BUILDING REGULATORY EFFICIENCIES

Since 9th PANDRH Conference

Advances in regulatory strengthening in the Region since the 9th Conference (2018)

Active Regional networks

Pharmacovigilance
Substandard and falsified medical products
Working group on medical devices
IMDRF Mirror Working Groups

Optimizing technical resources and regional expertise

Launch of the Central American Mechanism for the Joint Evaluation of Medicines Records

Evaluation of RS

Assisted self-benchmarking of the national RS in 21 Member States.
IDP defined for these countries.

Legal and organizational structures

Two NRAs were instituted or restructured:
Nicaragua and Paraguay

Strengthening regulation of medical devices

Landscaping on regulation of medical devices in the Region of the Americas completed in 22 countries.

Virtual courses

Number of participants

Biologics & biotechologicals in LA: 248
Medical devices in the Region of the Americas: +550
Pharmacovigilance: 1,222
Optimizing the use of antimicrobials (PROA): 635
Pharmaceutical Services: 277 beneficiarios

RS: Regulatory Systems

PAHO Pan American Health Organization World Health Organization Americas

RELIANCE IN PRACTICE

a model for small states with limited resources

Reliance | **Harmonization** | **Information sharing**

Caribbean Regulatory System (CRS):

Goals:

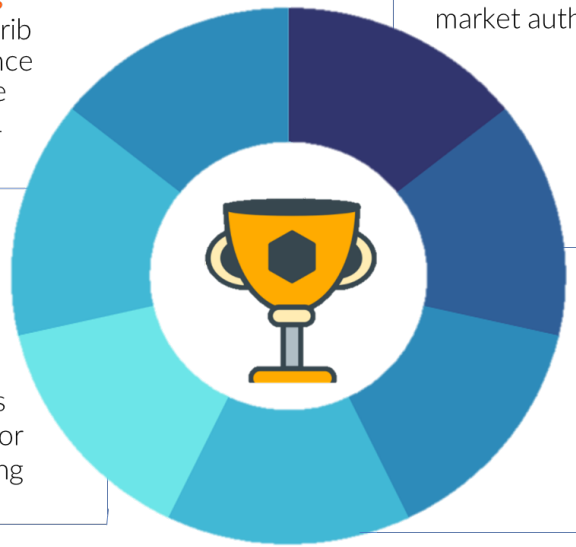
1. Access availability and affordability of essential medicines
2. Quality, safety and efficacy of essential medicines
3. Rational Use

Achievements:

- Policy stipulated the creation of a subregional regulatory framework to ensure the performance of essential regulatory functions.
- In 2016 CARICOM Ministers of Health agreed to the Creation of the CRS under CARPHA :
    1. Marketing Authorization
    2. Pharmacovigilance

PV: Ninety-nine case reports were shared with the VigiCarib network for pharmacovigilance and post-market surveillance in 2020: 98 medicines and 1 device (test kit)

Recommended +210 products for market authorization



Developed a monthly newsletter, VigiCarib news, regional view of case reports that are under investigation or pending action by neighboring countries

Recommended variety of products:

- Orphan drug for rare disease
- Biotherapeutics
- COVID-19 vaccines

Capacity building in dossier review in Member States

ADVANCES IN BUILDING REGULATORY EFFICIENCIES

Since 9th PANDRH Conference

Transparency and information sharing: Publicly available information on marketing authorizations of generics in NRAr

Smaller authorities, would benefit from more transparency of information from advanced authorities…

	ANMAT [a]	ANVISA [a]	CECMED [a]	COFEPRIS [a]	FDA [b*]	Health Canada [c*]	ISP [a*]	INVIMA [a*]	WHO FPP PQ [d]
Searchable electronic MA database	✓	✓	✓	✓	✓	✓	✓	✓	✓
Qualitative/quantitative formula									
Qualitative/quantitative formula								✓	✓
Authorized packaging									✓
Manufacturing site address			✓					✓	✓
TOTALS	**20%**	**20%**	**40%**	**20%**	**20%**	**20%**	**20%**	**60%**	**80%**

Note: * FDA and Health Canada make more information available for new products, including SMPC and product monograph.

Source: Regulatory System Strengthening in the Americas. Lessons Learned from the National Regulatory Authorities of Regional Reference. Washington, D.C.: Pan American Health Organization; 2021. License: CC BY-NC-SA 3.0 IGO.

REGULATORY PREPAREDNESS AND RESPONSE FOR PUBLIC HEALTH EMERGENCIES

How did the NRAs in the Region approach and respond to the pandemic?

Flexibility in regulations and processes

Learning and information sharing

+750 users

Reliance & Reduction of duplication efforts

Increase production capacities

- ✓ +30 facilitated discussions with NRA high-level focal points.
- ✓ Lessons learned among NRAs and work sharing promoted.
- ✓ Legal & policy frameworks for Regulators updated
- ✓ Regional Network to share regulator's best practices
- ✓ 30 regulators from LA NRAs supporting COVID-19 vaccines assessments
- ✓ Relevant information from PAHO, WHO, NRAr and access to major scientific journals shared through PANDRH List Server/PRAIS

- ✓ 25 Countries with access to EUL COVID-19 vaccine assessments
- ✓ Increased regulatory capacities for production expansion
- ✓ Forecasting tools to avoid pandemic shortages
- ✓ Dashboard to track vaccines safety evaluation criteria
- ✓ 75% of countries with exception of approval by the Ministry of Health for products procured through PAHO's Revolving and Strategic Funds

Key achievements for regulation and surveillance of COVID-19 vaccines developed in collaboration with regional NRAs

Regulatory documents

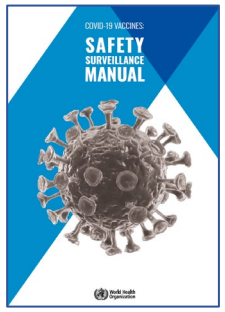
Regulatory oversight in the Pandemic: LINK

Q&A on regulatory matters: LINK

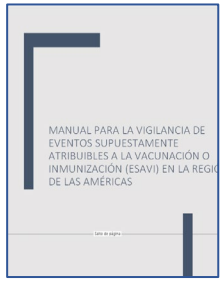
Post-authorization Surveillance of Medical Products: LINK

Reliance for Emergency Use Authorization: LINK

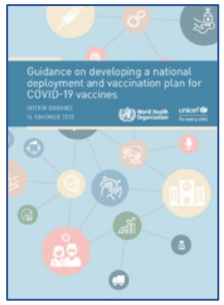
Manuals and guides



COVID-19 Vaccine safety surveillance manual: LINK



Regional surveillance manual



Guidance national deployment and vaccination plan for COVID-19 vaccines: LINK

Dashboard vaccine safety:

Pharmaco-vigilance Dashboard: Vaccine Safety Data and Research Phases LINK

Virtual course

ESAVI Regional Surveillance Course

Regulatory documents

Regulatory Processes of Introduction of COVID-19 vaccines: LINK

Regulatory Oversight of Clinical Trials: LINK

Regulation of medical devices in the context of COVID-19: LINK

Crisis management during epidemic: LINK

Challenges faced by NRAs in the Americas during the COVID-19 pandemic

Structural areas

- **Legal/regulatory instruments:** to reflect exceptional practices of authorization under emergencies
- **Sustainability/ efficiencies:** LA NRAr budgets have been stagnant or decreasing over the past few years
- Balance **regulatory stringency vs availability** of essential quality assured products
- **Communication** and **transparency** of information
- Insufficient availability of **human and financial resources** and the demand of switching to **24/7 operations**

Technical/ functional areas

Emergency Use Authorizations	Pharmacovigilance	Inspections	Clinical Data	Supply chain
-Evaluation of new technologies. -Submissions lacking complete data. -Assessment reports from other NRAs unavailable.	-Low rates of reporting of adverse drug reactions to global monitoring systems: LA countries represent less than 5% of all the reports in VigiBase.	-Onsite inspections affected due to restrictions.	-Translate scientific evidence (about the disease, vaccines) for decision-making and understanding of health personnel.	-Interruptions in the supply of medical equipment and health products, and lack of expertise, requirements and procedures for the evaluation of new technologies.

Inherent challenges exacerbated disruptions on continuity of essential health services during the COVID-19 pandemic

WHAT CAN WE DO BETTER?

- NRA need to become more efficient with the limited resources that we have, reliance and work sharing are key.
- NRA need to make risk-based decisions, follow reliance principles to develop legal frameworks and regulatory practices.
- NRA need to balance pre and post market focus (MA vs PV, GMP API vs finished product)
- Industry can play a critical role and contribute to the efficiencies by embracing transparency and enabling information sharing amogst regulatory bodies.

Although the Regulatory capacity of the Region has improved considerably in the last decade, it is necessary to continue the efforts…

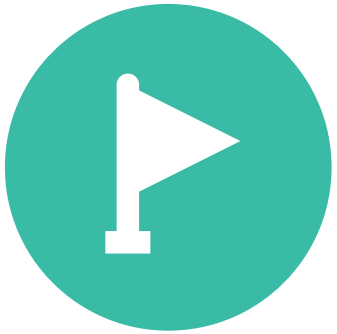
Building strong manufacturing capacities in emerging economies require development of integrated markets and for the local authority to have proper and full oversight of the specific product

OBJECTIVES OF THE 10TH PANDRH CONFERENCE

THE REGULATORY SYSTEMS IN THE HEALTH AGENDA POST COVID-19

Plenary 1

Strengthening, integration and pending agenda: the evolution of regulatory systems 2010-2020



Plenary 2

The contribution of the regulatory systems in the region of the Americas to the response of the COVID-19 pandemic

Plenary 3

The regulatory systems in the post COVID-19 agenda

ANNOUNCEMENTS

Announcements

Actions on the strategic development plan of PANDRH 2014-2020 to be discussed with the steering committee:

- Develop indicators to measure the implementation and impact of approved projects
- Carry out the evaluation of the strategic development plan of PANDRH 2014-2020 and define next steps
- Encourage the active participation of all NRA in ongoing projects and resume calls for new projects based on the needs of strengthening regulatory systems
- Define the 2022 work agenda to resume the thematic sessions not covered during this conference

Representation and Governance

PANDRH

Members of the Steering Committee with a mandate 2018-2021:

Subregion	Main	Alternate
North America	UNITED STATES	MEXICO
Central America + Cuba + Dominican Republic	EL SALVADOR	COSTA RICA
Caribbean	SURINAM	BAHAMAS
Andean Region	ECUADOR	CHILE
South Cone	URUGUAY	PARAGUAY
Observer members		
CRS	CARPHA	N/A
ARNr	ANMAT	N/A
ALIFAR*	RUBEN ABETE	MIGUEL MAITO
FIFARMA*	RAFAEL DIAZ-GRANADOS	MARIA FERNANDA HURTADO

*Founding members

Representation and Governance

PANDRH

Members of the Steering Committee with a mandate 2022- next Conference

Subregion	Main	Alternate
North America	MEXICO	CANADA
Central America + Cuba + Dominican Republic	HONDURAS	GUATEMALA
Caribbean	TBD	TBD
Andean Region	ECUADOR	TBD
South Cone	URUGUAY	PARAGUAY
Observer members		
CRS	CARPHA	N/A
ARNr	ANMAT	N/A
ALIFAR*	RUBEN ABETE	MIGUEL MAITO
FIFARMA*	RAFAEL DIAZ-GRANADOS	MARIA FERNANDA HURTADO

*Founding members

Pan American Health Organization

World Health Organization

REGIONAL OFFICE FOR THE Americas

PAHO