

PAHO regulatory arrangements to support regional procurement: reliance in practice

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The PAHO Revolving Funds for Access to Vaccines and Essential Medicines Procurement

1

Quality products

Precise technical specifications and special requirements are defined.

2

Technical assistance

Regulatory requirements in the country of destination, management of claims.

3

Aligned w/international standards

Documented decision for the acquisition of quality assured product without substitute role of an NRA.

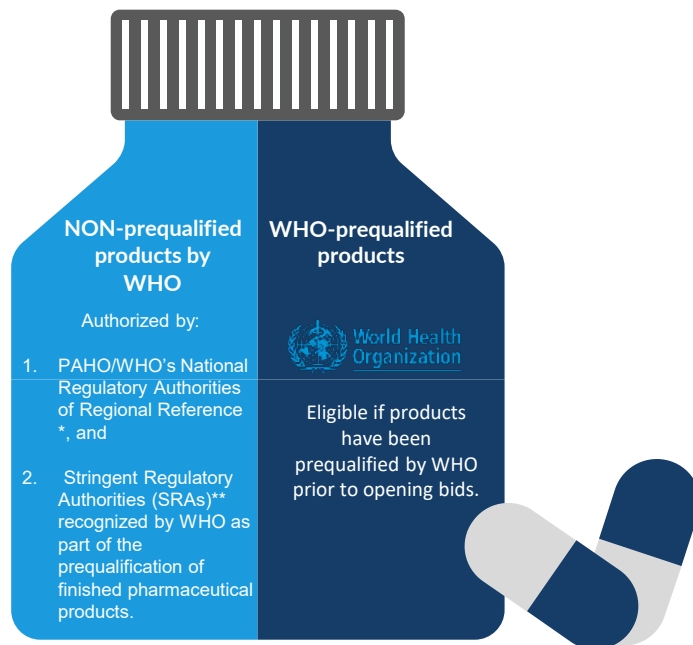
1. Central pillars for Disease Control and Elimination in the Americas

2. Based on principles of equity, universal access, quality and regional solidarity

3. The support of NRAR, has been a key factor in countries' confidence in the Funds.

NRAR: National Regulatory Authorities of Regional Reference

The PAHO Revolving Funds for Access to Vaccines and Essential Medicines Procurement



[*PAHO/WHO | System for Evaluation of the National Regulatory Authorities for Medicines](#)

[** List of Stringent Regulatory Authorities \(who.int\)](#)

Antiretrovirals: a product may be eligible if it has approval, or tentative approval by US FDA/PEPFAR.

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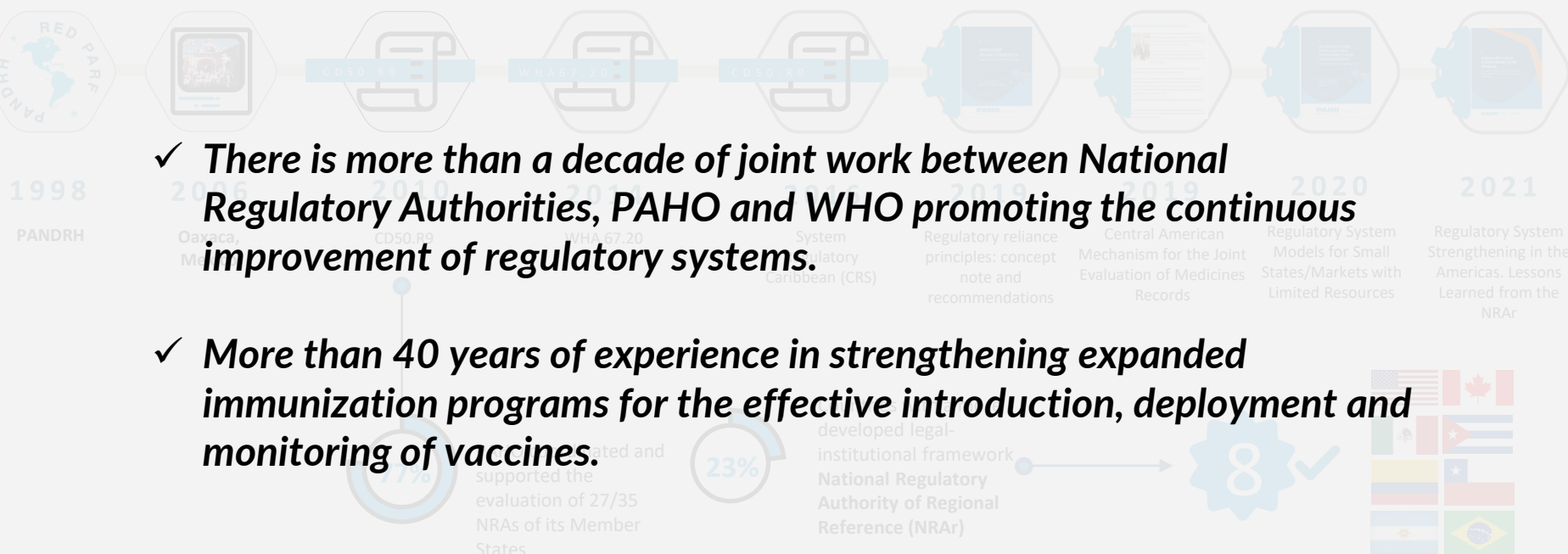
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NRAR: National Regulatory Authorities of Regional Reference

Laying the foundations

Regional bases of strengthened, stable, well-functioning, and integrated regulatory systems

- ✓ **There is more than a decade of joint work between National Regulatory Authorities, PAHO and WHO promoting the continuous improvement of regulatory systems.**
- ✓ **More than 40 years of experience in strengthening expanded immunization programs for the effective introduction, deployment and monitoring of vaccines.**



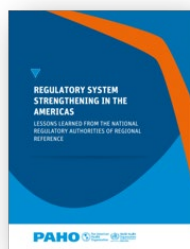
How does this translate to the regulatory arrangements to support regional procurement during the COVID-19 emergency response?

Best Practices and Efficiencies by NRAs in the Americas: reliance in practice

Regulatory preparedness and identification of gaps

- Exceptional approval mechanisms to import and authorize essential products for emergency response to be updated in national regulations.
- NRA needed access to real-time information from the trusted regulatory bodies to make risk-based decisions and keep up to date the approval of essential products for emergency response.
- NRA needed to balance pre and post-market focus (e.g. MA vs PV).

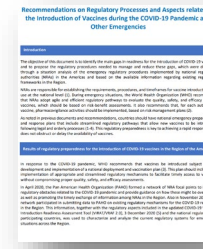
Although the regulatory capacity of the Region has improved considerably in the last decade, it is necessary to continue the efforts...



[Regulatory System Strengthening in the Americas. Lessons Learned from the National Regulatory Authorities of Regional Reference \(paho.org\)](https://paho.org/public/amr/509/document/Regulatory-System-Strengthening-in-the-Americas-Lessons-Learned-from-the-National-Regulatory-Authorities-of-Regional-Reference.pdf)



[Reliance for Emergency Use Authorization of Medicines and Other Health Technologies in a Pandemic \(e.g. COVID-19\) \(paho.org\)](https://paho.org/public/amr/509/document/Reliance-for-emergency-use-authorization-of-medicines-and-other-health-technologies-in-a-pandemic-e-g-covid-19.pdf)



[Recommendations on Regulatory Processes and Aspects related to the Introduction of Vaccines during the COVID-19 Pandemic and Other Emergencies \(paho.org\)](https://paho.org/public/amr/509/document/Recommendations-on-regulatory-processes-and-aspects-related-to-the-introduction-of-vaccines-during-the-covid-19-pandemic-and-other-emergencies.pdf)

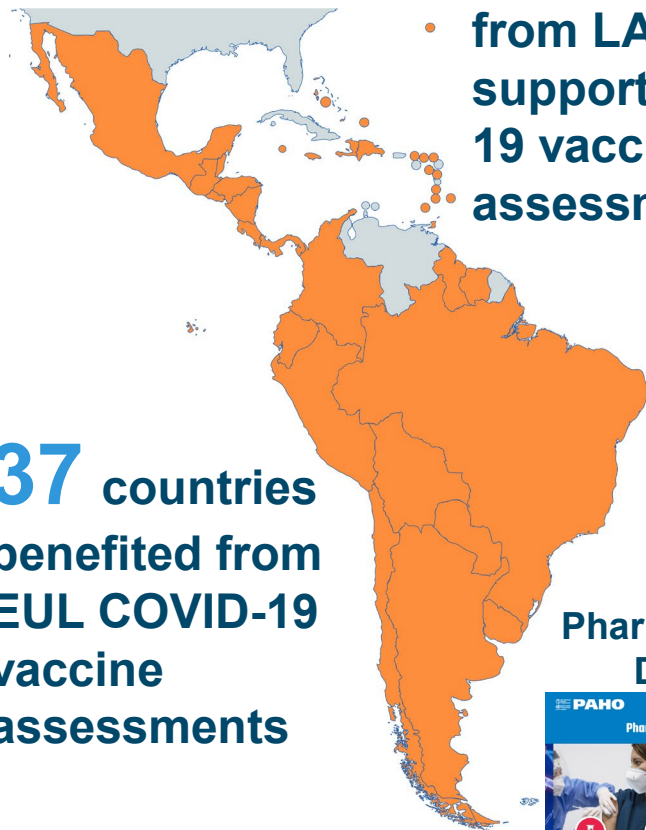
Regional support for introduction and monitoring of COVID-19 vaccines: PAHO strategic cooperation

+30 regulators
from LA NRAs
supporting COVID-
19 vaccines
assessments

+30 meetings with
NRA high-level focal
points

Provided assessment for
+1M doses of COVID-19
vaccines impacted by
temperatures excursions

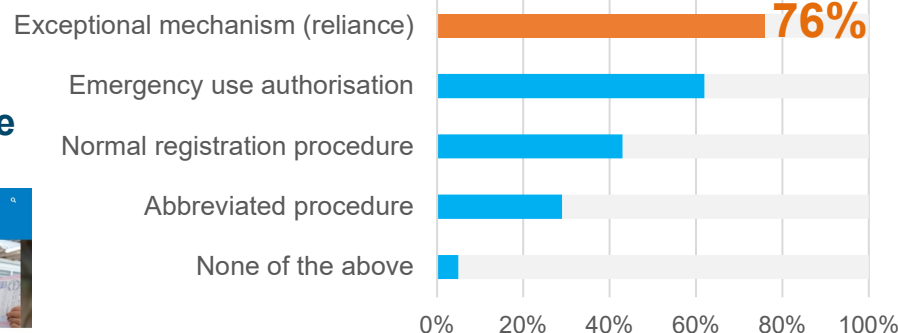
37 countries
benefited from
EUL COVID-19
vaccine
assessments



Pharmacovigilance Dashboard



Regulatory mechanisms for COVID-19 vaccine approval used by 21
National Regulatory Authorities in the Americas, November 2020



Regional support for introduction and monitoring of COVID-19 vaccines: PAHO strategic cooperation

Covid-19 Procurement Portal

Home > Product Information

Doses Allocated

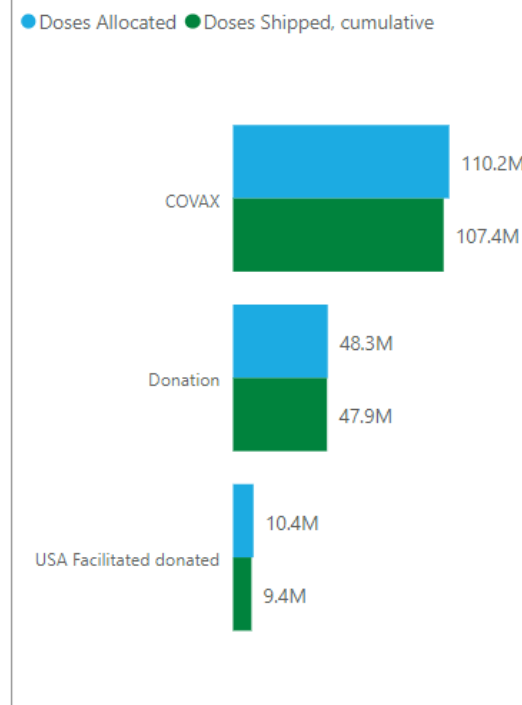
168,910,130

Countries and territories,
doses shipped

34

unicef

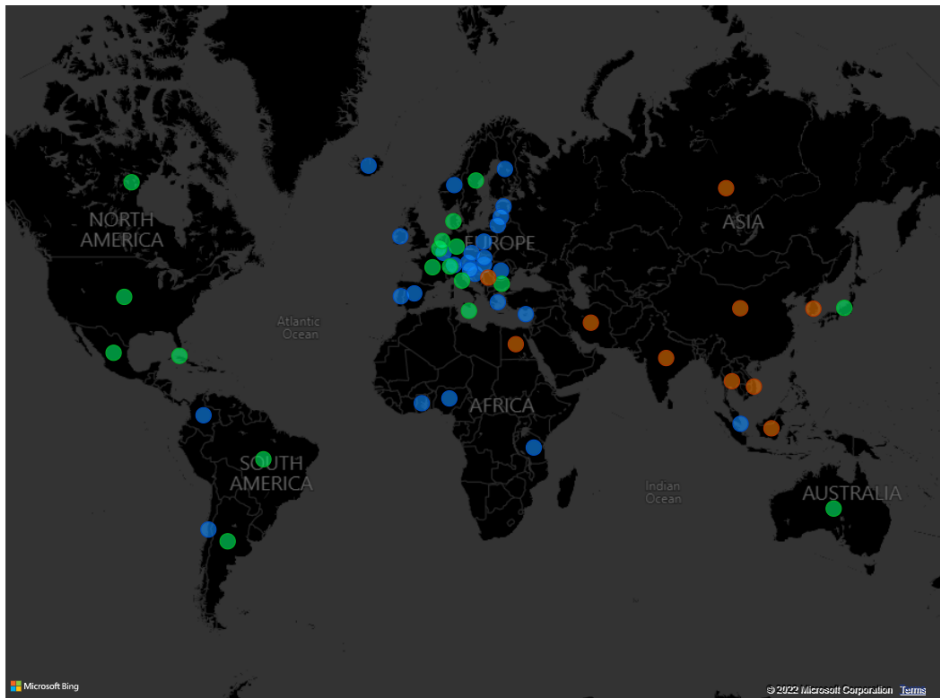
- ✓ The exceptional mechanisms for local approvals/import permits of current COVID-19 vaccines used by Member States were applied.
- ✓ No regulatory barriers were identified during this time frame related to the introduction of vaccines during the COVID-19 pandemic.



Preparing for the WLA framework

Country and scope of the transitional list of WHO Listed Authorities

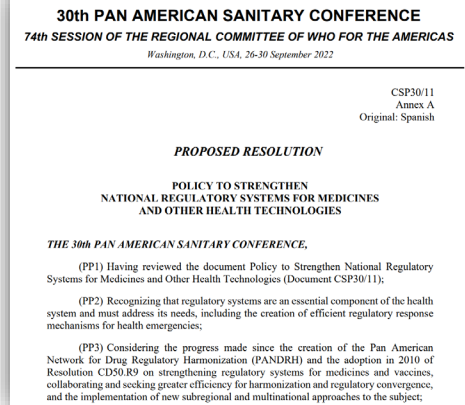
Scope of the tWLA designation ● Medicines ● Medicines + Vaccines ● Vaccines



NRA	Origin of transition
ISP	D
INVIMA	D
Health Canada	B, C, D, E
FDA	A*
COFEPRIS	D, E
CECMED	D, E
ANVISA	D, E
ANMAT	D

A ML3*/ML4** NRA (medicines/vaccines)
 B SRA (medicines)
 C Highly performing NRA (vaccines)
 D NRA of the Americas (medicines/vaccines)
 E Functional NRA (vaccines)

No. CSP30/11



Source: [List of transitional WLAs \(who.int\)](https://www.who.int/publications/m/item/list-of-transitional-wlas)

Note: The tWLA list is valid for five years from the date of publication of the final WLA Operational Guidance

- **Maintain recognition of Regional capacities at the international level**
- **PAHO's role in continuously working towards the strengthening of regulatory systems**
- **Continue to promote the use of reliance and regulatory efficiencies and their incorporation into national regulations**

