

# The benefits of convergence with international standards

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On behalf of FIFARMA

VIII Conference of the Pan American Network on Drugs Regulatory Harmonization | Mexico City | 19 to 21 October



# Outline

- Initiatives of regulatory convergence across time
- Multilateral agreements in the Region: political decisions supporting convergence and harmonization
- NRA networks in the Region: mutual knowledge and reliance
- Benefits of convergence
- How to move farther and faster?

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# Chronology of main international initiatives on regulatory convergence



Source: Silva APJ, Tagliari, POP. Regulatory initiatives in health in the Americas: history, evolution and new challenges. Rev Panam Salud Publica 2016; 39(3);210-16

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# MERCOSUR: implementation of compatible sanitary control systems, technical cooperation and legislation harmonization are included in the mandate of Workgroup 11 – “Health”

MERCOSUR/GMC/RES. Nº 13/07

**PAUTA NEGOCIADORA DEL SGT Nº 11 "SALUD"  
(DEROGACIÓN DE LA RES. GMC Nº 06/05)**

## PAUTAS DE ACCIÓN

- Armonizar legislaciones y directrices, promover la cooperación técnica y coordinar acciones entre los Estados Partes en el área de la salud necesaria al proceso de integración.
- Compatibilizar los sistemas de Control Sanitario de los Estados Partes, con miras a fortalecer el proceso de integración en el ámbito del MERCOSUR.

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# PACIFIC ALLIANCE: Convergence and harmonization with international standards are among the steps to reduce technical barriers to trade established by the Additional Protocol to the Framework Agreement of the Pacific Alliance

## CAPÍTULO 7 OBSTÁCULOS TÉCNICOS AL COMERCIO

### ARTÍCULO 7.5: Cooperación y Facilitación del Comercio

1. Las Partes buscarán identificar, desarrollar y promover iniciativas que faciliten el comercio, que sean apropiadas para asuntos o sectores determinados, en relación con normas, reglamentos técnicos y procedimientos de evaluación de la conformidad, tomando en consideración la respectiva experiencia de las Partes en otros acuerdos bilaterales, regionales o multilaterales que sean apropiados. Entre otras, tales iniciativas podrán consistir en:

- (d) favorecer la convergencia o la armonización con las normas internacionales, y

# SICA: the Protocol to the General Framework for Central America Economic Integration (Protocol of Guatemala) provides for regional regulatory harmonization and adoption of common technical requirements.

PROTOCOLO AL TRATADO GENERAL DE INTEGRACION  
ECONOMICA CENTROAMERICANA  
(*PROTOCOLO DE GUATEMALA*)

LOS GOBIERNOS DE LAS REPÚBLICAS DE COSTA RICA,  
EL SALVADOR, GUATEMALA, HONDURAS, NICARAGUA Y PANAMÁ

## Artículo 26

Los Estados Parte se comprometen a armonizar y adoptar normas y reglamentos técnicos comunes de mercado que se dirigirán únicamente a satisfacer los requerimientos para la protección de la salud humana, animal y vegetal, el medio ambiente, la seguridad y el cumplimiento de estándares mínimos de calidad.

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# PAHO's DIRECTING COUNCIL (2010): urge countries to engage with PANDRH convergence initiatives in the context of the efforts to strengthen the NRA in the region

## *RESOLUTION*

### *CD50.R9*

#### STRENGTHENING NATIONAL REGULATORY AUTHORITIES FOR MEDICINES AND BIOLOGICALS

1. To urge the Member States to:

- (f) actively participate in the Pan American Network for Drug Regulatory Harmonization (PANDRH).

# NRA networks in the Americas enabling mutual knowledge and reliance

Robust, long-lasting and comprehensive networks of regulatory authorities in the region dedicated to:

- ✓ Technical and scientific cooperation
- ✓ Information exchange
- ✓ Work sharing
- ✓ PAHO's Regulatory Authorities of Regional Reference

## Much has been built in terms of mutual knowledge and reliance among NRAs in the Americas

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# Benefits of regulatory convergence

## ✓ Patients

- More expedited access to medicines
- Maintenance or improvement of safety, efficacy and quality standards

## ✓ Regulators

- Reduction of regulatory workload, cost and time
- More collaborative and efficient use of resources
- Increased opportunities for work sharing

## ✓ Regional Integration

- Facilitation of trade
- Easier alignment of public policies

## ✓ Industry

- Reduction of general regulatory burden
- Facilitated businesses planning

# How to move farther and faster with regulatory convergence initiatives?

states. The VII Conference of the Pan American Network for Drug Regulatory Harmonization (CPANDRH) (Ottawa, Canada, 5–7 September 2013)<sup>5</sup> recognized this challenge when it adopted its Strategic Development Plan 2014–2020, which calls for 1) active participation of NRAs toward regulatory convergence and harmonization; 2) the integration of PANDRH work with other international initiatives; and 3) the identification of priorities, strategies, and mechanisms for regulatory convergence and harmonization in the Americas.

Source: Pombo ML, Porrás A, Saidon PC, Cascio SM. Regulatory convergence and harmonization: barriers to effective use and adoption of common standards. *Rev Panam Salud Publica*. 2016;39(5):217–25.

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# Regulatory convergence in Americas: “take-aways” from the industry perspective

- ✓ Conditions for convergence are consolidated in the continent: sovereign decisions supporting convergence and a solid network among NRA have been established across years in the Region, enabling mutual knowledge and reliance
- ✓ Move towards effective regulatory convergence is beneficial for patients, regulators, regional integration initiatives and the industry
- ✓ **Under PAHO/PANDRH leadership and with industry/NRA collaboration, the election of priority and feasible topics for a work agenda on regulatory convergence and the integration of PANDRH work with other international initiatives would foster convergence in the region and prevent fragmentation of efforts**
- ✓ Ongoing initiatives could be enhanced towards more convergence and collaboration: Ex.: Caribbean Regulatory System project covering also innovative drugs

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