Regulatory Systems’ Strengthening in Americas: Regional Approaches to Regulatory Convergence

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Technical cooperation approach for RSS in the Americas

1. Facilitating the development of context-specific national regulatory systems
2. Promoting regulatory convergence and harmonization
3. Supporting the efficient use of resources by leveraging the work of others
The objective of this system is to facilitate the establishment of mechanisms for cooperation among regulatory authorities in the Region and progress toward possible inter-institutional recognition, with the consequent optimization of human and financial resources.

Oaxaca, 2006
FIGURE 1. Rate of use of PANDRH TDs, 23 Americas Region, 1999–2013

GLP
- 32% (59%)
- 14% (68%)
- 9% (32%)
- 59% (14%)

GPV
- 18% (50%)
- 55% (55%)
- 18% (18%)
- 68% (18%)

GMP
- 27% (27%)
- 55% (55%)
- 18% (18%)
- 50% (50%)

GCP
- 32% (32%)
- 50% (50%)
- 50% (50%)

SBP
- 18% (46%)
- 36% (36%)
- 36% (36%)
- 46% (46%)

VAC
- 14% (45%)
- 45% (45%)
- 54% (54%)
- 45% (45%)

SSFFC
- 11% (11%)
- 63% (63%)
- 54% (54%)
- 63% (63%)

BE
- 14% (32%)
- 32% (32%)
- 32% (32%)
- 32% (32%)

Source: compiled by the authors based on the study results.

- Pan American Network for Drug Regulatory Harmonization Technical Documents.
- GLP: TD on self-evaluation of good laboratory practices; GPV: TD on good pharmacovigilance practices for the Americas; GMP: TD on good manufacturing practices inspection; GCP: TD on good clinical practices for the Americas; SBP: TD on evaluation of similar biotherapeutic products; VAC: TD on harmonized requirements for licensing of vaccines in the Americas and guidelines for preparation of applications; SSFFC: TD for health authorities on suspected counterfeit medical products; BE: TD on framework for implementation of equivalence requirements for pharmaceutical products.

Blue shading: survey participant reported country used the TD; orange shading: survey participant reported country did not use the TD; grey shading: survey participant did not respond to the question.

Medicines Regulatory Systems Core Elements

**PRINCIPLES**
- Independence
- Equity
- Transparency
- Ethical
- Code of conduct
- Absence of conflict of interest
- Risk Management Plan
- Accountability
- Regulatory Science

**CROSS-CUTTING ELEMENTS**
- Legal basis
- Standard, guidance, specifications, and procedures
- Financing and other resources
- Quality assurance system
- Competent human resources
- Information systems

**CORE REGULATORY FUNCTIONS ACROSS MAJOR PRODUCTS CATEGORIES**
- National Regulatory System Framework
- Registration and marketing authorization
- Licensing activities
- Post-marketing surveillance (including lot release for vaccines)
- Oversight of clinical trials
- Inspections and enforcement activities
- Laboratory access and quality testing
- Others (no common across specific products, such as: vigilance and risk management, control of promotion and advertising, control of narcotics, psychotropic substances and precursors, pharmaceutical personnel)
To the Member States:

- Strengthen and evaluate their regulatory capabilities through an assessment of the performance of their essential functions;
- Promote the dissemination of information on the results and processes for the regulation;
- Promote interaction and technical cooperation among countries.
Towards functional national regulatory systems

Institutional development plan
- priority setting
- clear goals based on gap analysis and context

Technical support
- bilateral/multilateral
- NRAr
- networks
- direct technical cooperation

Evaluation

Pan American Health Organization
World Health Organization
Regional Office for the Americas
Participation implies that the Member State:

- Adopts an IDP based on the assessments
- Allows that the results can be shared (except of protected and confidential information) with participating NRAs
- Allows for the publishing of aggregated regional/sub-regional data
5.2 veces usuarios desde Julio 2012

- 70 nuevas personas
- 7 instituciones en 2016

PRAIS en números – Oct, 2016

Medical Devices (basic indicators)

15 countries

Medicines (Advanced Indicators)

21 countries

• 2 nuevas CoP en 2016 (Mm antituberculosos y Radiological Health)
Regional Regulatory Profile

**68.8%**  
Basic regulatory capacities  
[March 2014]

**61%**  
Regulatory System  
[April 2015]

**69%**  
Marketing Authorization  
[November 2016] (editing)
Functional Level of the National Regulatory Authority

- **Level IV**: defined as a competent and efficient national regulatory authority that performs the health regulatory functions recommended by PAHO/WHO for guaranteeing the quality, safety, and efficacy of medicines and biologicals. *Regulatory authority of regional reference.*
- **Level III**: defined as a national regulatory authority that needs to improve its performance of certain health regulatory functions recommended by PAHO/WHO for guaranteeing the quality, safety, and efficacy of medicines and biologicals.
- **Level II**: defined as structures or organizations with a national regulatory authority mandate that perform certain health regulatory functions recommended by PAHO/WHO for guaranteeing the quality, safety, and efficacy of medicines and biologicals.
- **Level I**: defined as divisions of health institutions that perform certain health regulatory functions for medicines and biologicals.
Strengthening Regulatory Authorities in Medicines and Biologics (CD50.R9), 2010
The regulatory authorities of regional reference will:

a) Participate in processes for guaranteeing the quality, safety, and efficacy of products procured by the Pan American Health Organization on behalf of the countries.

b) Collaborate as reference centers in implementing and monitoring the recommendations of PANDRH.

c) Collaborate with the Pan American Health Organization in activities to strengthen other national regulatory authorities in the Region so they can be designated as regulatory authorities of regional reference.

d) Share public information online within the framework of current national legislation on the products approved by the regulatory authorities of regional reference. This will give authorities with less capacity tools for making decisions about their own products, as the products registered and marketed in countries with regulatory authorities for regional reference will meet WHO’s recommended quality standards.
Achievements and impact of an initiative in which all countries of the Region, regardless of their level of development participate and benefit

What are the implications?

1. Adoption of IDP,
2. Regulatory profiles are made public,
3. Identification of strengths and weaknesses, prioritization, identification and establishment of partnerships/joint work plans supported by NRAr
4. Prioritization of harmonization and regulatory convergence activities.

Why does it work?

1. Member State driven, formal mandate, coordinated response.
2. Promotes transparency and limits bias,
3. Engaging countries in regional technical cooperation practices (paradigm shift).
Regulatory Exchange Platform secure (REPs): Background

- PAHO’s PRAIS platform required a secure environment to share inspection reports (PRAISEC).
- Member states who participate in the Medical Device Single Audit Program (MDSAP) asked PAHO to leverage and converge the efforts of PRAISEC, MDSAP and potentially other global initiatives.
- TGA, ANVISA, Health Canada, Japan (MHLW/PMDA) and FDA provided initial funding and technical support for the project.
What’s REPs?

• Regulatory Exchange Platform – secure (REPs) is an IT solution to support the secure exchange of regulatory non-public information (NPI) to inform and support regulatory decision making among National Regulatory Authorities (NRAs).

• REPs is designed as a modular platform to support the secure information exchange of current and future initiatives.
What’s REPs?

Previous

PRAISEC

PRAIS

REPs

MDSAP

PRAISEC

PANDRH

Potential areas to consider

ACSS Work Sharing

IGDRP ASMF WG
A new trend towards convergence in the development of the regulatory systems in the Americas

- In the Americas there is increasing international cooperation to strengthen the regional regulatory capacity.
- Cooperation is mainly based on the sharing of information, convergence and reliance of regulatory processes, not in the absolute harmonization of norms and standards.
- A national regulatory system perspective and capacity building is central to the region’s convergence efforts.
Thank you!