Platforms for promoting the exchange of information between regulators

Fernanda Lessa – HSS/MT (PAHO/WHO)
Information sharing: Background & Mandates
Promoting regulatory convergency & harmonization

- The Pan American Network for Drug Regulatory Harmonization (PANDRH), 1999
  - **Mission**: To promote regulatory harmonization, including the quality, safety, efficacy and the rational use of pharmaceutical products, while strengthening the capacities of National Regulatory Authorities (NRAs).


- **CD50.R9 (2010)** – Strengthening NRAs for medicines and biologicals:
  - Promote the dissemination of information on the results and processes for the regulation and oversight of medicines, biologicals, and other health technologies;
  - Promote interaction and technical cooperation among countries;
  - Support initiatives for the strengthening and qualification of NRA to guarantee the quality, safety, and efficacy of medicines, biologicals, and other health technologies;

- **WHA 67.20 (2014)** – Regulatory system strengthening for medical products
  - To promote international cooperation, as appropriate, for collaboration and information sharing, including through electronic platforms.
  - To support regulatory system strengthening as an essential component of the development or expansion of local or regional production of quality, safe and efficacious medical products;

- **VIII PANDRH Conference (Mexico, 2016)**
  - Development of national regulatory capacities – convergence – and the use of Good Regulatory Practices and Regulatory Sciences;
  - Use **PRAIS** and Regulatory Exchange Platform-secure (REPs) to create opportunities for regulatory collaboration inside and outside the region.

PAHO/WHO
PAHO's approach?

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
- Laboratory access and quality testing

PAHO/WHO Medicine Regulatory Systems Core Elements

PAHO's approach?

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PAHO's approach?

PAHO's approach?
Supporting the efficient use of resources by leveraging the work of others
Promoting regulatory convergence & harmonization

**PRAIS – Regional Platform on Access and Innovation for Health Technologies**

- **7310 visits (Jan-Jul 2018)**
- **2719 Regional Info posts**
- **1755 users (2018)**
- Information & data for 42 countries:
  - Medicines regulation: 34 countries
  - Medical devices: 15 countries
  - Blood: 42 countries
  - Radiology health: 9 countries

http://prais.paho.org/
**REDMA Program**

*Exchange of Reports on Adverse Events of Medical Devices*

- Online tool for the exchange of medical devices adverse events reports between NRAs, strengthening surveillance systems in the Region.
- Repository of medical devices adverse events reports.
- Pilot exercise completed, with the participation of 10 countries (Argentina, Brazil, Chile, Colombia, Cuba, Mexico, El Salvador, Panama, Dominican Republic and Uruguay); 12 reports exchanged
- Launch expected for 14 Dec 2018.
Cloud solution to enable the exchange of regulatory non-public information to inform and support regulatory decision making among National Regulatory Authorities in a secure environment.

- Versatile module approach allowing expansion and tailor needs to additional initiatives
- Currently with 2 modules: MDSAP and RISE

Exclusive module for NRAs to share regulatory information, strengthening regulatory system through a collaborative process

- NRAs control over the process
- PAHO has no access to the content
- MOU with PAHO and Confidential agreement among parties are needed to join these initiatives
- Virtual training
Importance of the platforms: Regulatory Systems Strengthening

- Information sharing – highlights
  - transparency
  - regulatory harmonization
  - regulatory capacity strengthening
  - reliance practices in the Region
  - dissemination of results and processes for the regulation and oversight of medicines, and other health technologies;
  - interaction and technical cooperation among countries;
- Allows the development of data sharing metrics to guide international cooperation without requiring access to the content (REPs).
- Cost effective: secure tools owned by NRAs, supported by PAHO with global implications