Platforms for promoting the exchange of information between regulators

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PAHO/WHO

Information sharing:

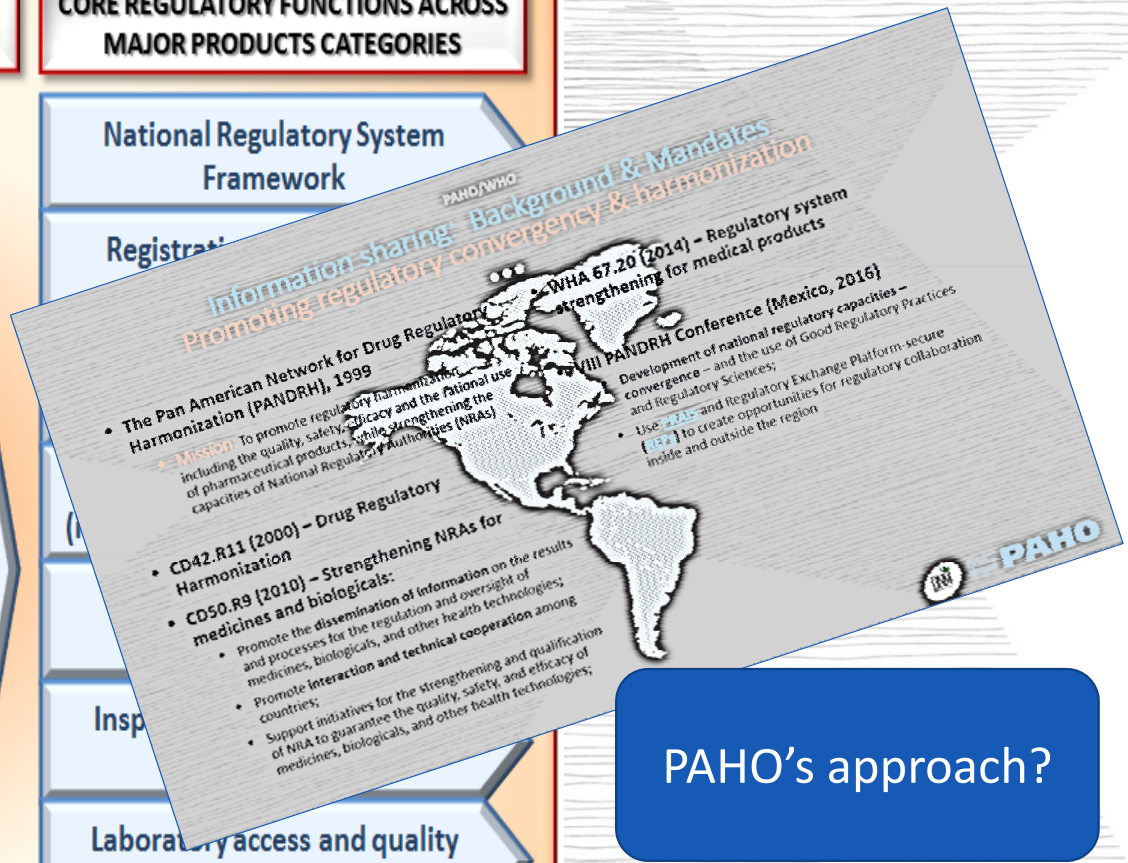
PAHO

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)
- **CD42.R11 (2000) – Drug Regulatory Harmonization**
- **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

Medicine Regulatory Systems Core Elements

PRINCIPLES	CROSS-CUTTING ELEMENTS	CORE REGULATORY FUNCTIONS ACROSS MAJOR PRODUCTS CATEGORIES
• Independence • Equity • Transparency • Ethical • Code of conduct • Absence of conflict of interest • Risk Management Plan • Accountability • Regulatory Science	• Legal basis • Standard, guidance, specifications, and procedures • Financing and other resources • Quality assurance system • Competent human resources • Information systems	National Regulatory System Framework Registrat… (… Insp… Laborat…y 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



PAHO's approach?

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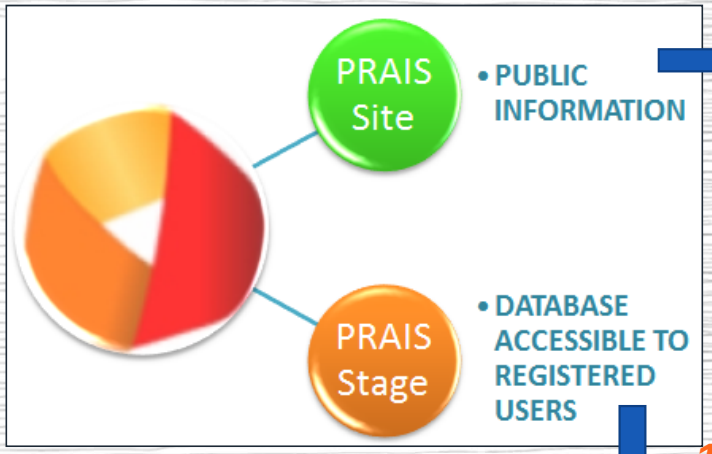
Supporting the efficient use of resources by leveraging the work of others
Promoting regulatory convergence & harmonization

PRAIS – Regional Platform on Access and Innovation for Health Technologies



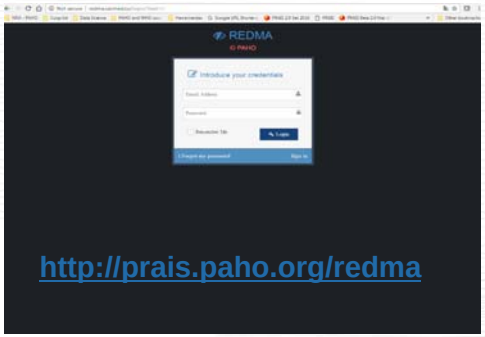
7310 *visits (Jan-Jul 2018)*

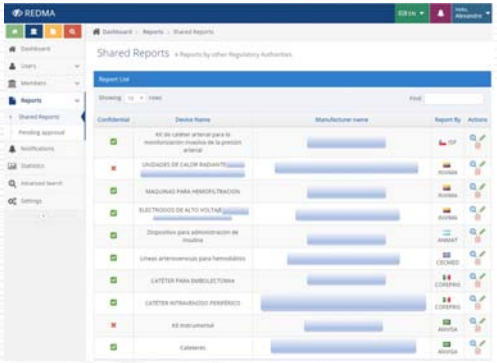
2719 Regional Info posts

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, strenghthening 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.

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REPs

Regulatory Exchange Platform – secure

- 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**

RISE

Regulatory Information Secure Exchange

- **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 Strengthtening

- **Information sharing – highlights**

  PROMOTES

  - 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, suppported by PA HO with global implications

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