Regulatory Policy in Resource Constrained Countries:
Partnership for Capacity Development

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**Good Manufacturing Practices**
- 33% Fully adopted
- 61% Partly adopted
- 6% Not adopted

**Implementation of equivalence requirements**
- 21% Fully adopted
- 63% Partly adopted
- 16% Not adopted

**Good Laboratory Practices**
- 13% Fully adopted
- 87% Not adopted

**Counterfeit / Falsified medical products**
- 22% Fully adopted
- 50% Not adopted
- 28% Partly adopted

**Good Clinical Practices**
- 27% Fully adopted
- 46% Partially adopted
- 27% Not adopted

**Good Pharmacovigilance Practices**
- 21% Fully adopted
- 21% Partially adopted
- 58% Not adopted

**Licensing of vaccines**
- 47% Fully adopted
- 21% Partially adopted
- 32% Not adopted

**Similar Biotherapeutics Products**
- 56% Fully adopted
- 5% Partially adopted
- 39% Not adopted
Assessment of 25 countries using 20 indicators measuring basic regulatory functions and capacity;

- 69% of basic indicators achieved;
- 14 of 25 countries achieved more than 75%

Source: PAHO/WHO PRAIS 2014
Prioritizing Regulatory Systems Development

- Institutional development of NRA in process for:
  - Bahamas, Costa Rica, Chile, Colombia, Dominican Republic, Ecuador, El Salvador, Guatemala, Guyana, Honduras, Panama, Paraguay, Peru, Suriname, Trinidad & Tobago.

- Currently, there are seven WHO/PAHO reference regulatory authorities
  - Argentina, Brazil, Canada, Colombia, Cuba, Mexico and the United States of America

- WHO/PAHO Collaborating Centers:
  - US FDA (CBER), Health Canada (HPFB), Cuba (Medical Devices)
Regional NRA Priorities (2013) (I)

Survey of 29 NRAs (2013); priorities by product category for capacity development

- Medical devices
- Biotechnology
- Biologics/Vaccines
- Herbal medicines
- Blood derivatives
- Medicines (Synthetic route)
- Others
Regional NRA Priorities 2013 (II)

Survey of 29 NRAs (2013); priorities by regulatory process for capacity development
National Regulatory Policy guided by Increasing NRA Cooperation

- Multiple new agreements signed between NRAs: e.g.
  - Strengthening of regulatory capacity (Mexico / El Salvador)
  - Sharing of GMP inspection reports (Argentina, Brazil, Colombia, Cuba)
  - Recognition of medical device product registrations (US / Costa Rica)

- Capacity building between regulators: e.g.
  - Multicountry participation in Health Canada’s HPFB International Regulatory Forum 2011 – 2014 (vaccines and medical devices)
  - Annual FDA/CDER International Regulatory Forum
  - ANMAT International courses on falsified products, PV etc

- Cooperation through collaborative networks; e.g.
  - 10th Annual Step for the PAHO/WHO External Quality Control Program with 23 countries and 26 OMCLs
  - Establishment of a Regional Network of Pharmacovigilance Focal Points within NRAs (2012)
  - IMDRF: with participation of Canada, US and Brazil
National Regulatory Policy guided by Increasing Regional / Global NRA Cooperation

• ALBA (July 2013) towards a Regional Center and Single Registry for Medicines

• Central America: development of roadmap for regulatory systems development (2013) (Mesoamerica Initiative)

• Linkages between PAHO Member States and APEC, IMDRF, IMRA etc

• CARICOM; towards a sub-regional regulatory framework strengthening regulatory systems in the Caribbean;
**Caribbean Regulatory System (CRS)**

- The CRS will become a regulatory unit for CARICOM Member States based within CARPHA (Trinidad & Tobago).
- A Pilot project for registration of multisource (generic) medicines approved by Ministers of Health, Caribbean, September 2015.
  - high priority disease areas for CARICOM and CARPHA Member States, specifically medicines for acute infections as well as non-communicable diseases;
  - registration process will be based on an abbreviated review procedure that will leverage information on registration and marketing authorizations granted by Reference Authorities and/or WHO Prequalification and place the burden of providing this information on the manufacturer.
  - Supported by US FDA and Argentina; pending discussions with Brazil and Mexico. Technical guidance from PAHO/WHO
Partnerships in Regulatory Policy in the Americas

• NRAs are transitioning towards the concept of Regulatory Systems Development as a core element of national regulatory policy:
  o Prioritization of regulatory legal frameworks, structure and quality management systems;
  o Definition of core regulatory functions based on national policy objectives;
  o Cooperation with partner / reference NRAs is core to current regulatory policy for NRAS, independent of resource level;
  o Implicit with current regulatory policy is leveraging regulatory decisions on those taken by more well established / resourced NRAs;
  o Tendency towards regulatory convergence as opposed to harmonization;

• International partners; PAHO/WHO, Gates, World Bank.

• Private Sector; through the Pan American Network for Drug Regulatory Harmonization (PANDHR)
PANDHR Strategic Development Plan 2014-2020

- Adopted by the VII PANDHR Conference, Ottawa, Sep 2013, comprised of NRAs, Industry Associations, Academia and NGOs;

- Strategic objectives (SO) of the Plan;
  
  o SO I. Promote the efficient governance of PANDRH and the active participation and cooperation of NRAs moving towards regulatory convergence and harmonization
  
  o SO II. Periodically define strategies and mechanisms for regulatory convergence and harmonization, and support their dissemination, adoption, and implementation by NRAs
  
  o SO III. Promote the strengthening of competencies in Good Regulatory Practices and Regulatory Sciences
  
  o SO IV. Promote the exchange of experiences and regulatory knowledge between NRAs within PANDRH, as well as with NRAs outside of the Region.

- Industry, Academia and NGOs will play a critical support role in the implementation of this plan.
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