Regulatory Policy in Resource Constrained Countries:

Partnership for Capacity Development

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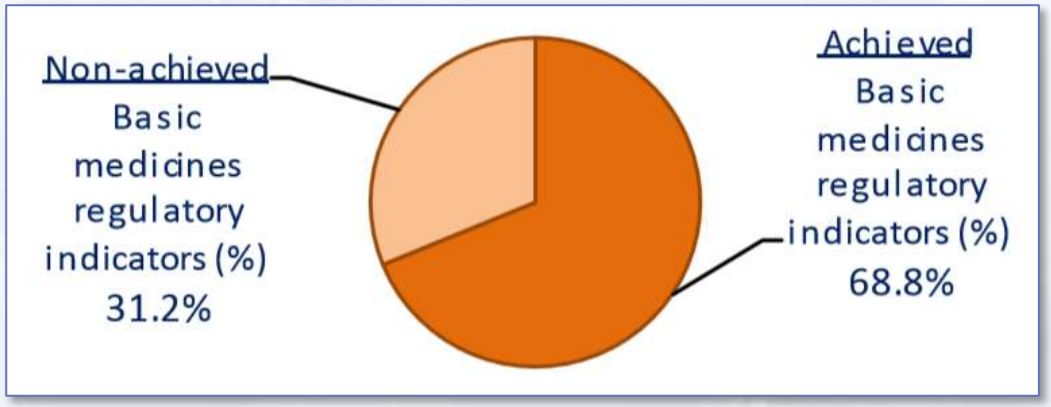
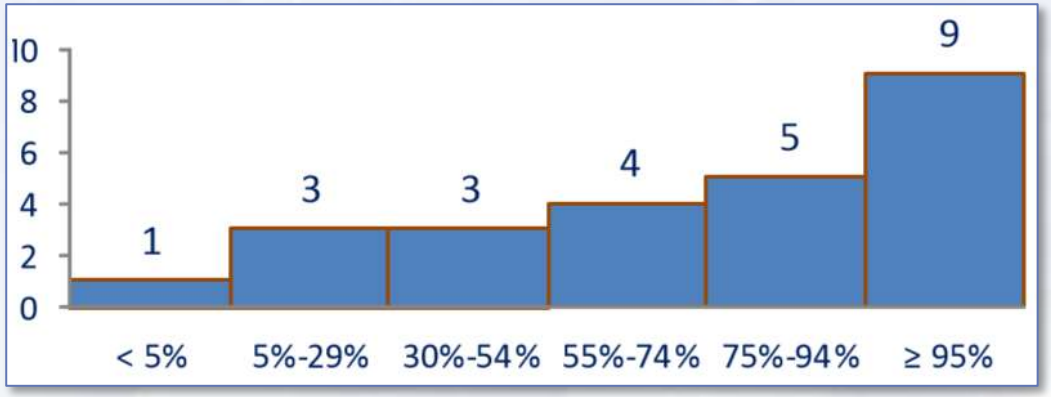
Regulatory Capacity Overview in the Americas





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: PRAIS 2014

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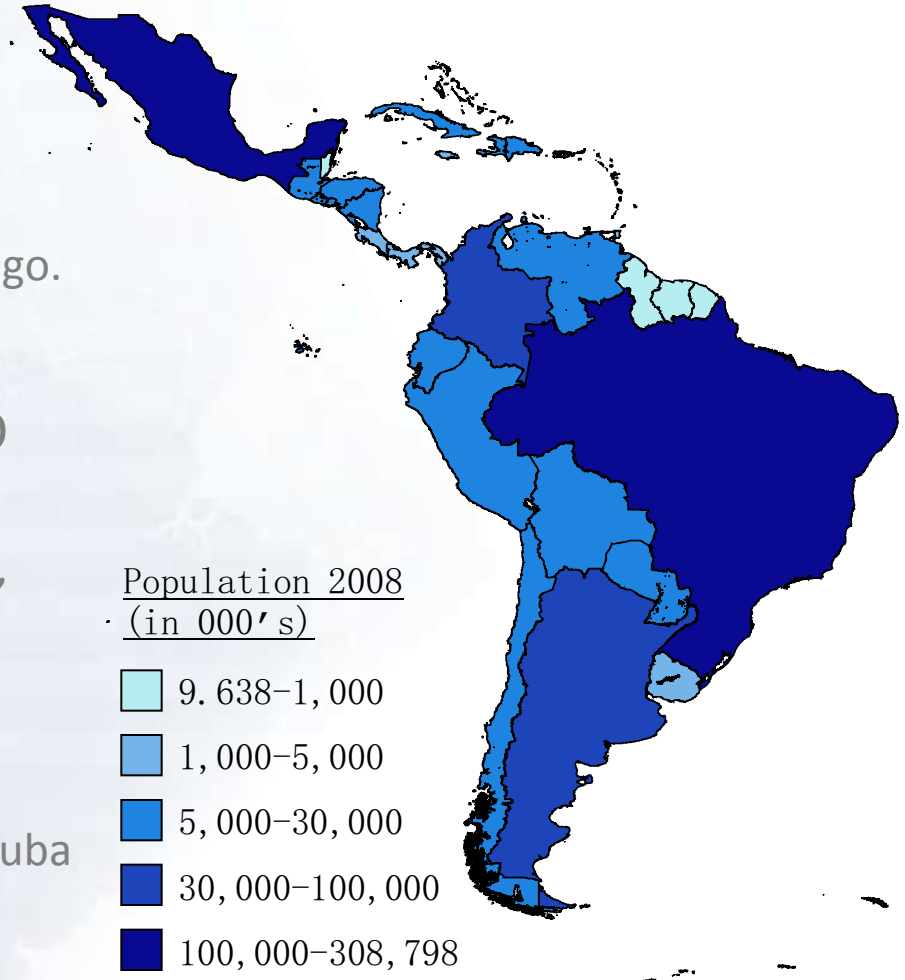
Prioritizing Regulatory Systems Development

- 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)



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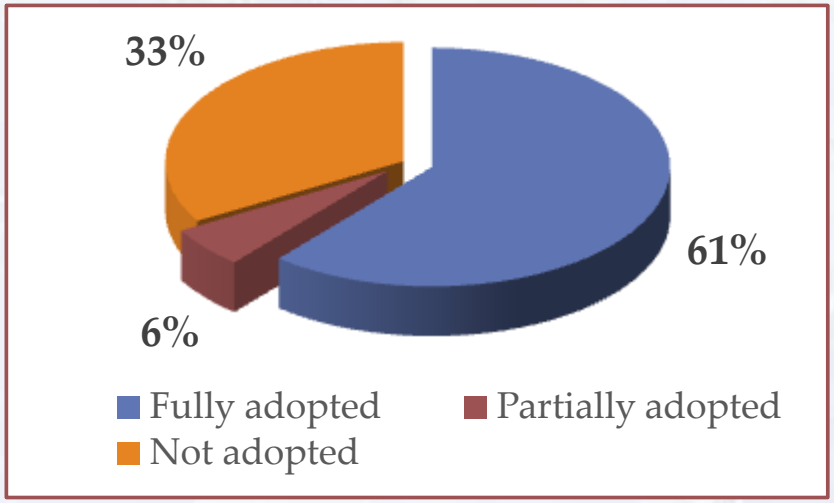
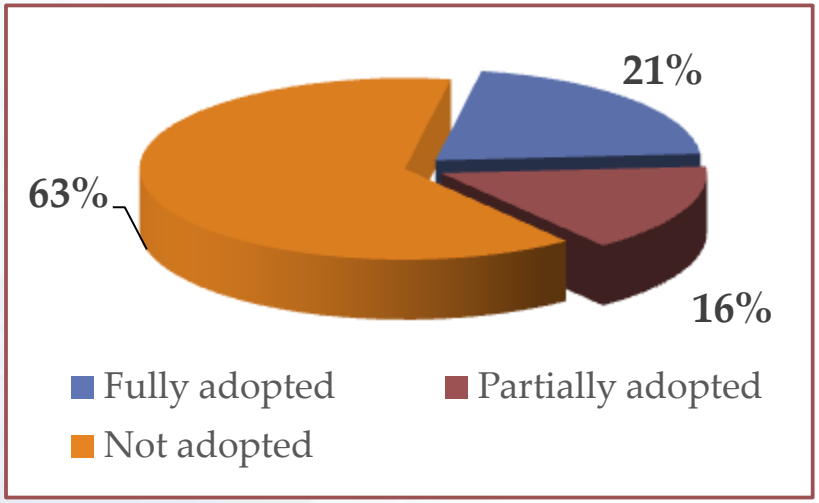
Implementation of PANDHR Guidelines (2013)

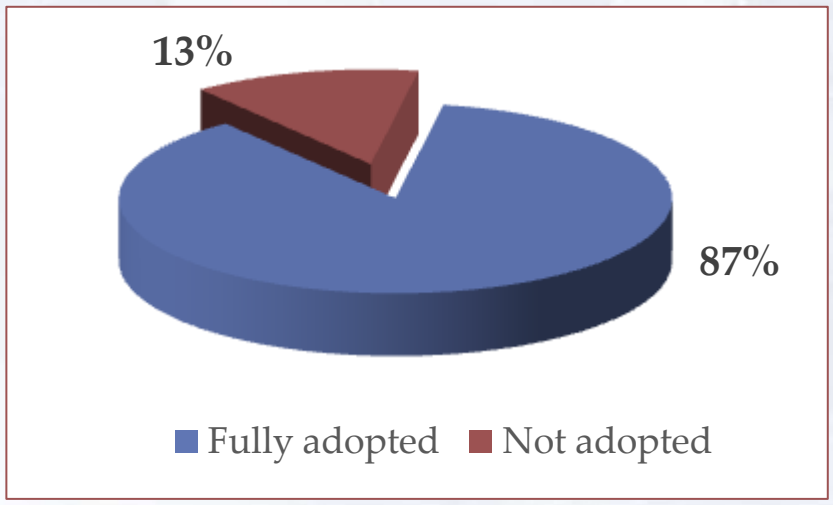
Good Manufacturing Practices



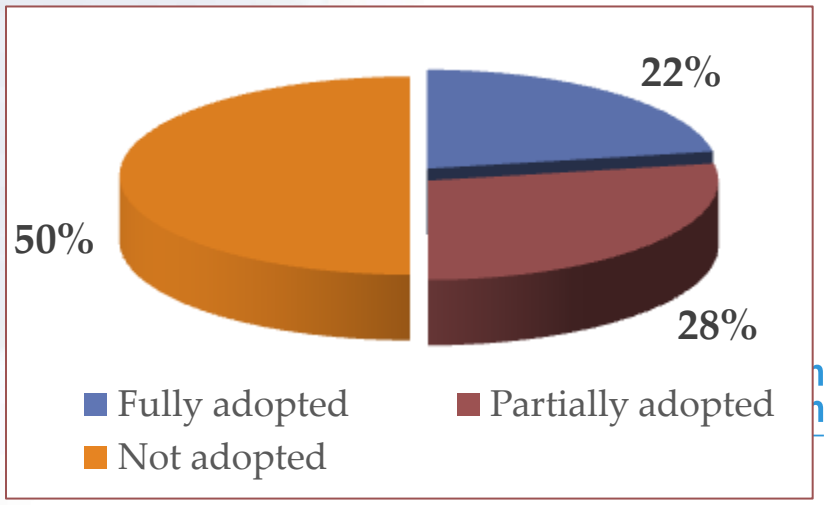
Implementation of equivalence requirements



Good Laboratory Practices

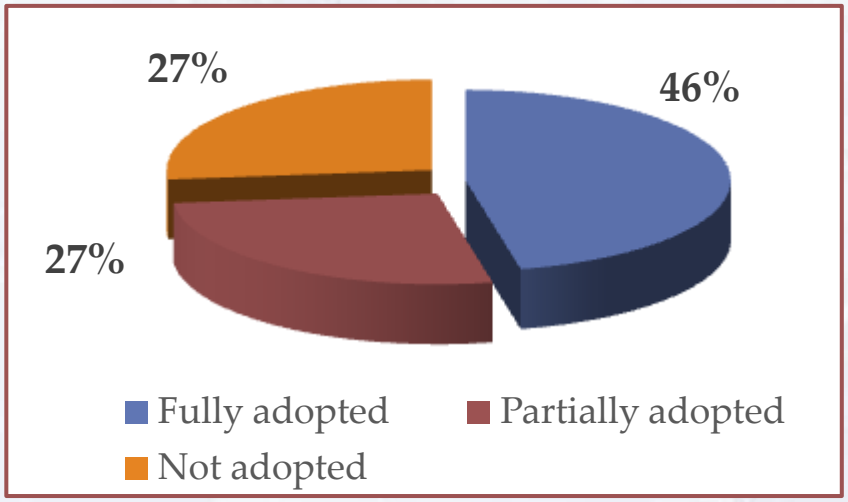


Counterfeit / Falsified medical products

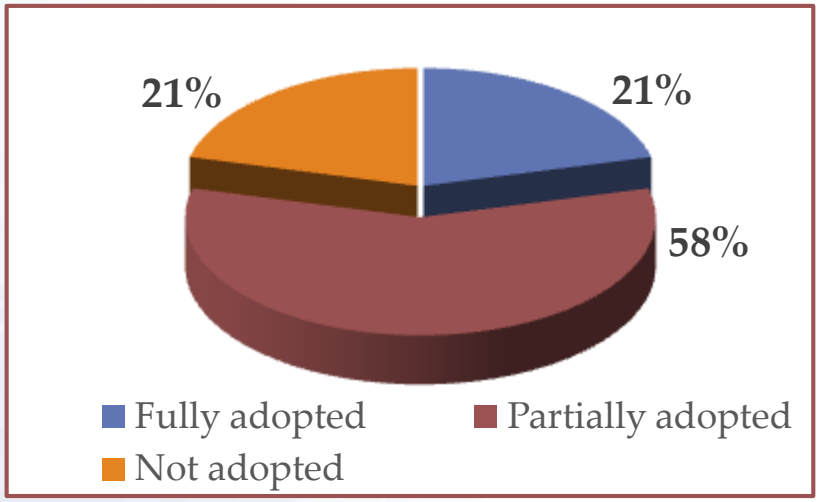


Implementation of PANDHR Guidelines (2013)

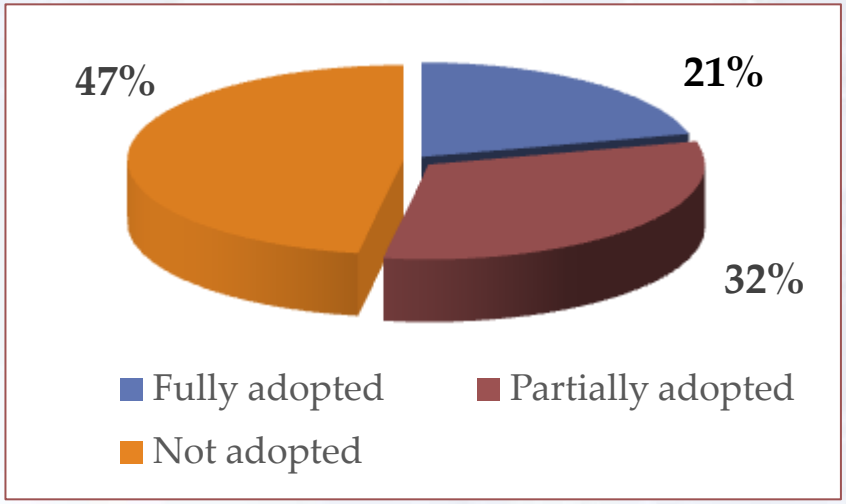
Good Clinical Practices



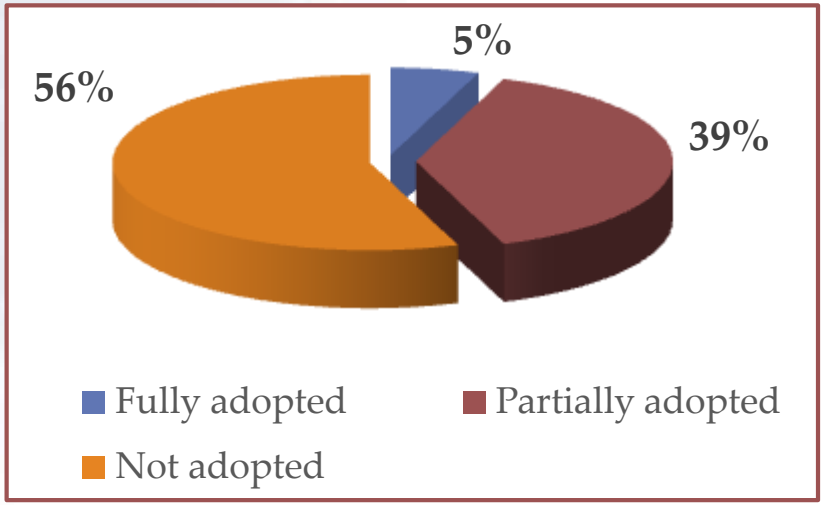
Good Pharmacovigilance Practices



Licensing of vaccines

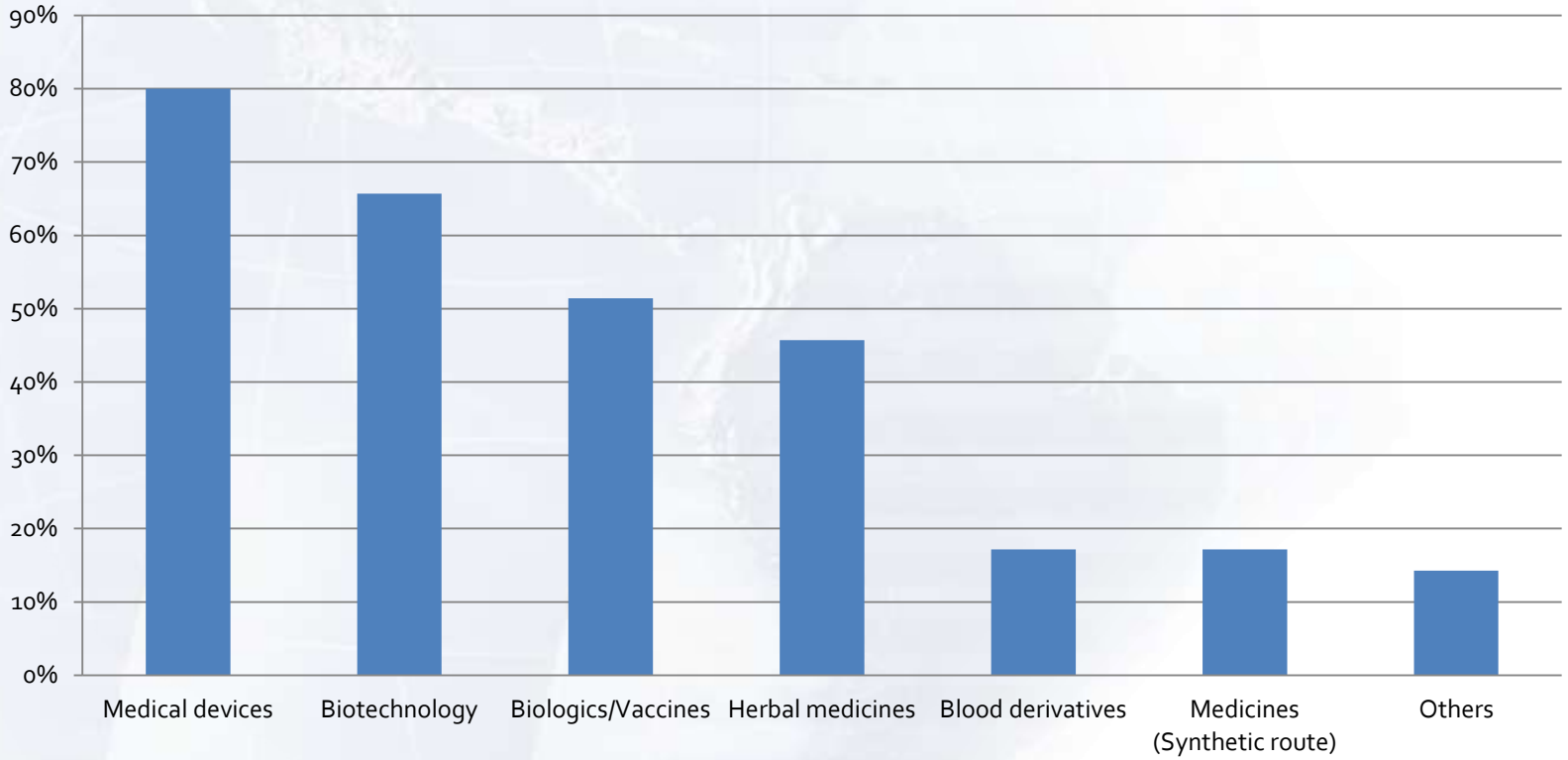


Similar Biotherapeutics Products



Regional NRA Priorities (2013) (I)

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



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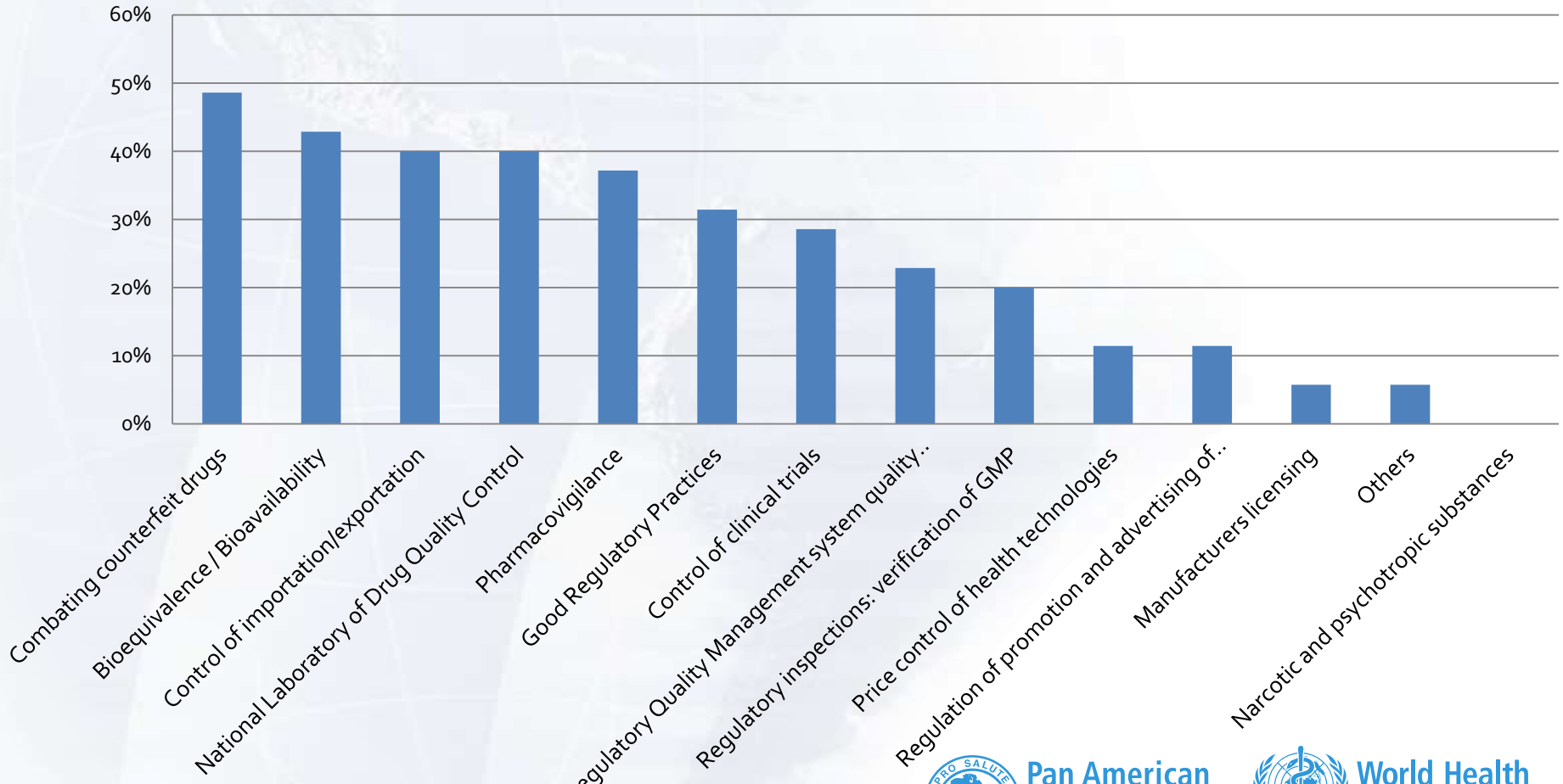
Regional NRA Priorities 2013 (II)

Survey of 29 NRAs (2013); priorities by **regulatory process** for capacity development



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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 and 2012 (vaccines and medical devices)
  - 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

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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;

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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:
  - Prioritization of regulatory legal frameworks, structure and quality management systems;
  - Definition of core regulatory functions based on national policy objectives;
  - Cooperation with partner / reference NRAs is core to current regulatory policy for NRAS, independent of resource level;
  - Implicit with current regulatory policy is leveraging regulatory decisions on those taken by more well established / resourced NRAs;
  - 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)

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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;
  - SO I. Promote the efficient governance of PANDRH and the active participation and cooperation of NRAs moving towards regulatory convergence and harmonization
  - SO II. Periodically define strategies and mechanisms for regulatory convergence and harmonization, and support their dissemination, adoption, and implementation by NRAs
  - SO III. Promote the strengthening of competencies in Good Regulatory Practices and Regulatory Sciences
  - 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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