PANDRH STRATEGIC DEVELOPMENT PLAN 2014-2020:

RATIONALE, REGIONAL CONTEXT AND LESSONS LEARNED

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OUTLINE

- PANDRH: 1999 - 2013
- Regulatory Systems Development and Cooperation in the Region
- Implementation of PANDRH Guidelines within a complex global regulatory environment
- NRA Priorities in the Americas; an overview
- The PANDRH Strategic Development Plan 2014 - 2020

PANDRH:1999 - 2013

- The Pan American Network for Drug Regulatory Harmonization (PANDRH) was established in 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)

- Six Conferences organized to present, discuss and adopt normative guidelines developed by Working Groups

- PANDHR has supported capacity building, implementation of normative guidelines, exchange of experience between NRAs

VI PANDRH CONFERENCE, BRAZIL, 2011;

- Adoption of Technical Documents:
  - Recommendations for the evaluation of similar bio-therapeutic products (SBP);
  - Guidelines for the Registration of Medicines in the Americas;
  - Manual for research / Guidelines for Good Clinical Practices;
  - Guidelines for Clinical Trials in Pediatrics;
  - Considerations on the use of placebo in Clinical Trials;
  - Ethical criteria for the promotion, advertising of medicines.
- A call for the development of a Strategic Plan for PANDRH that integrates NRA systems development (CD50R9 / 2010):
  - Network flexibility, promoting cooperation and exchange between NRAs;
  - Focus on development of regulatory systems;
  - Design and implement regional training program with NRAs of reference and other entities (universities).
- Use new and existing platforms to create opportunities for collaboration.

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 with regulatory functions assessed:
  - Argentina, Brazil, Canada, Colombia, Cuba, Mexico and the United States of America

- WHO/PAHO Collaborating Centers:
  - US FDA (CBER), Health Canada (HPFB), Cuba (process initiated)

INCREASING REGIONAL 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
  - Communities of practice through PRAIS

COMPLEX REGIONAL / GLOBAL REGULATORY LANDSCAPE

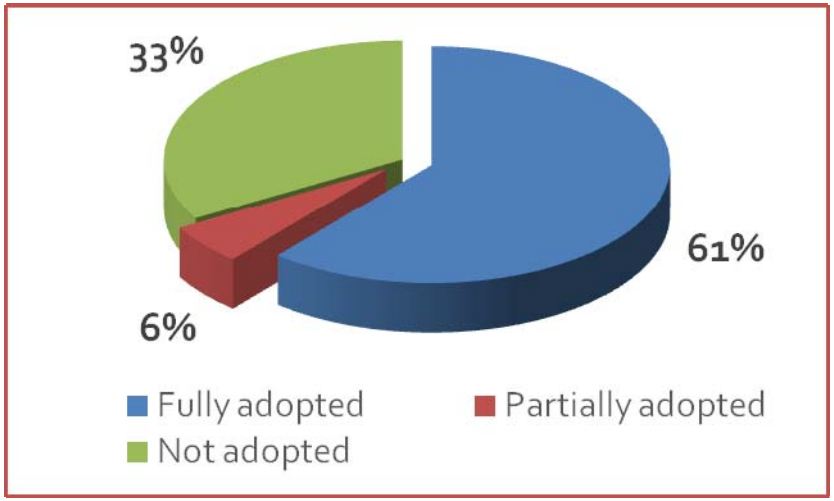
- Sub-regional developments:
  - CARICOM; towards a sub-regional regulatory framework strengthening regulatory systems in the Caribbean
  - ALBA (July 2013) towards a Regional Center and Single Registry for Medicines
  - Central America: development of roadmap for regulatory systems development (2013)

- NRAs establishing collaborative links with Global Initiatives / alternative harmonization or regulatory convergence initiatives:
  - WHO / ICDRA
  - ICH / APEC / ICH
  - IMDRF
  - PIC/S
  - Trans Pacific Partnership / Regulatory Coherence

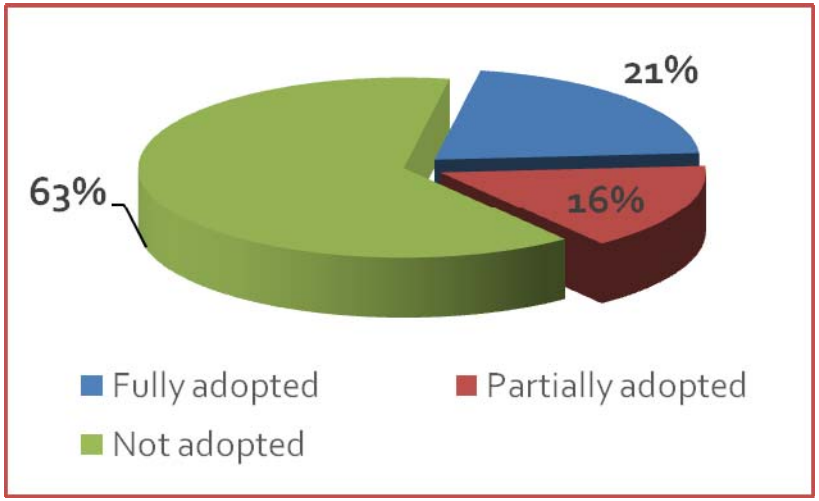
HAVE PANDHR GUIDELINES BEEN ADOPTED / IMPLEMENTED? (I)

Extend to which technical documents have been adopted by NRAs in the Americas:

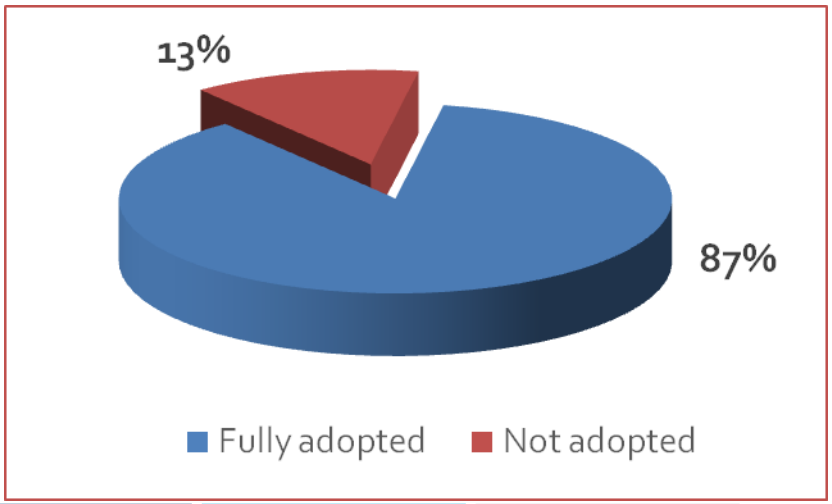
Good Manufacturing Practices



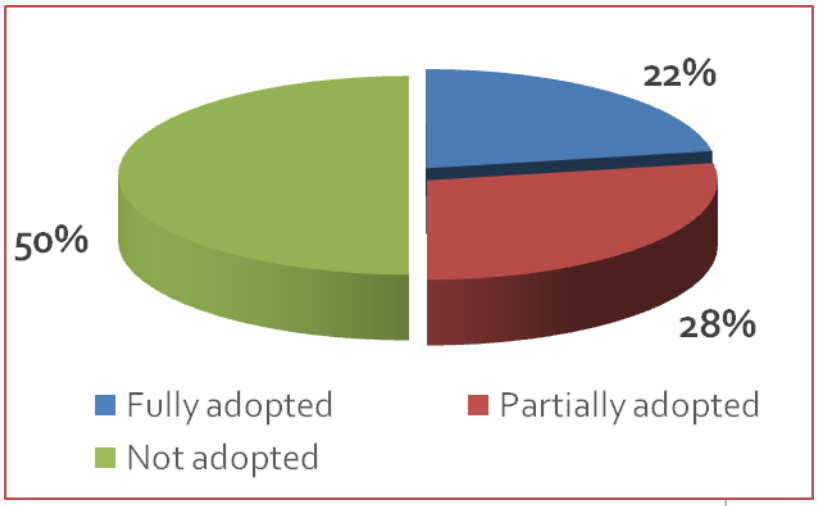
Implementation of equivalence requirements



Good Laboratory Practices



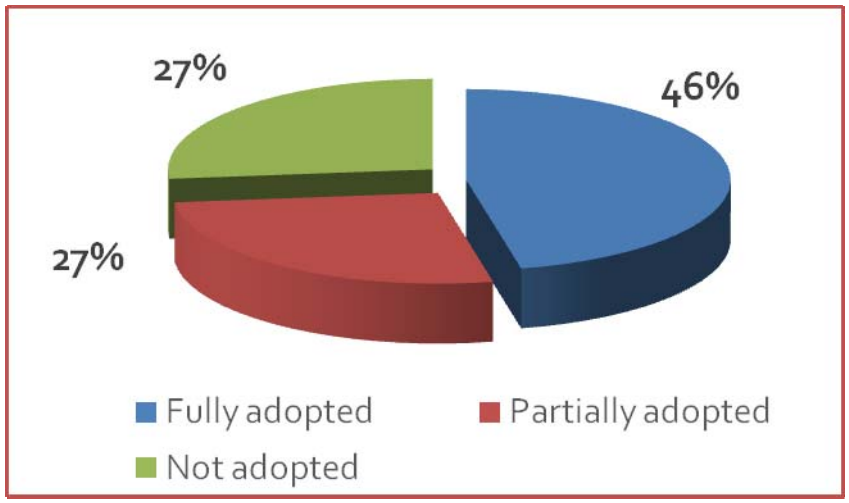
Counterfeit / Falsified medical products



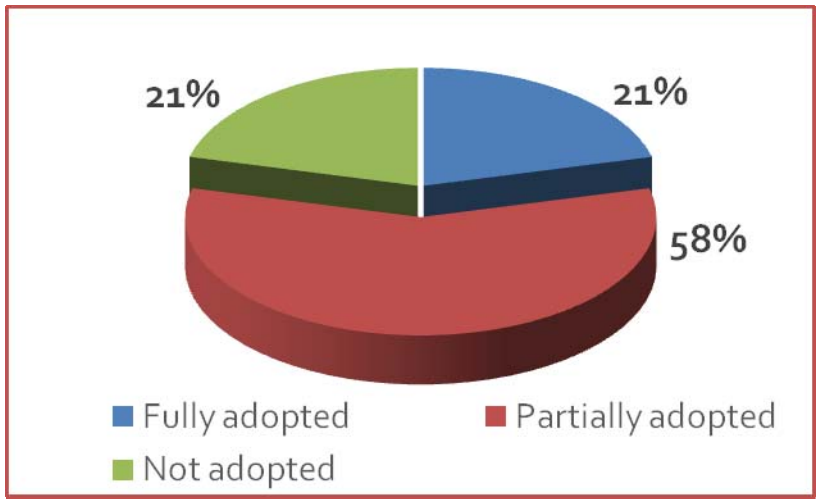
HAVE PANDHR GUIDELINES BEEN ADOPTED / IMPLEMENTED? (II)

Extend to which technical documents have been adopted by NRAs in the Americas:

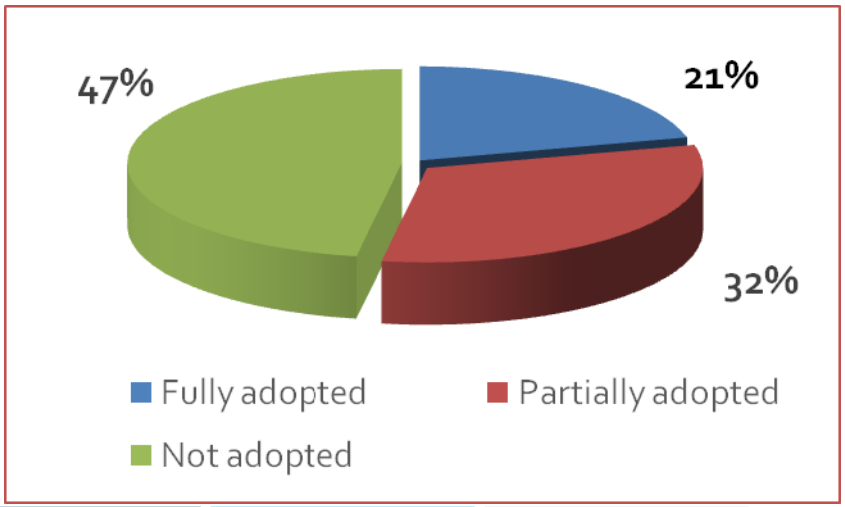
Good Clinical Practices



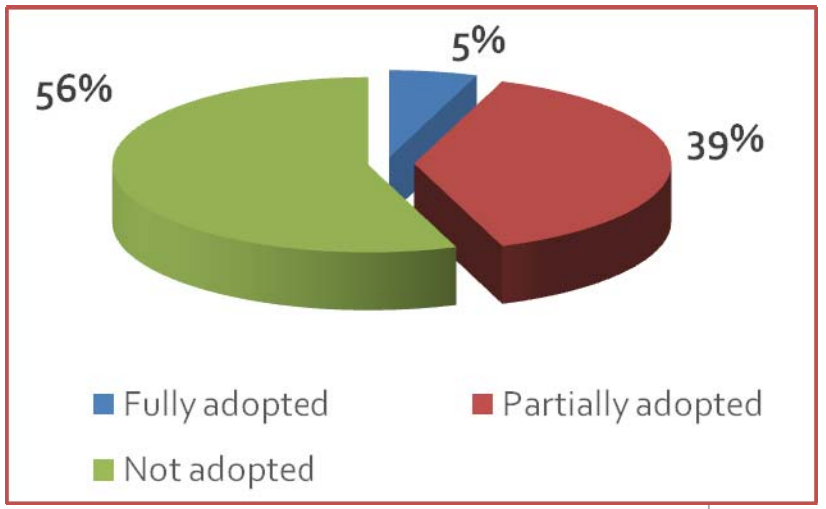
Good Pharmacovigilance Practices



Licensing of vaccines



Similar Biotherapeutics Products

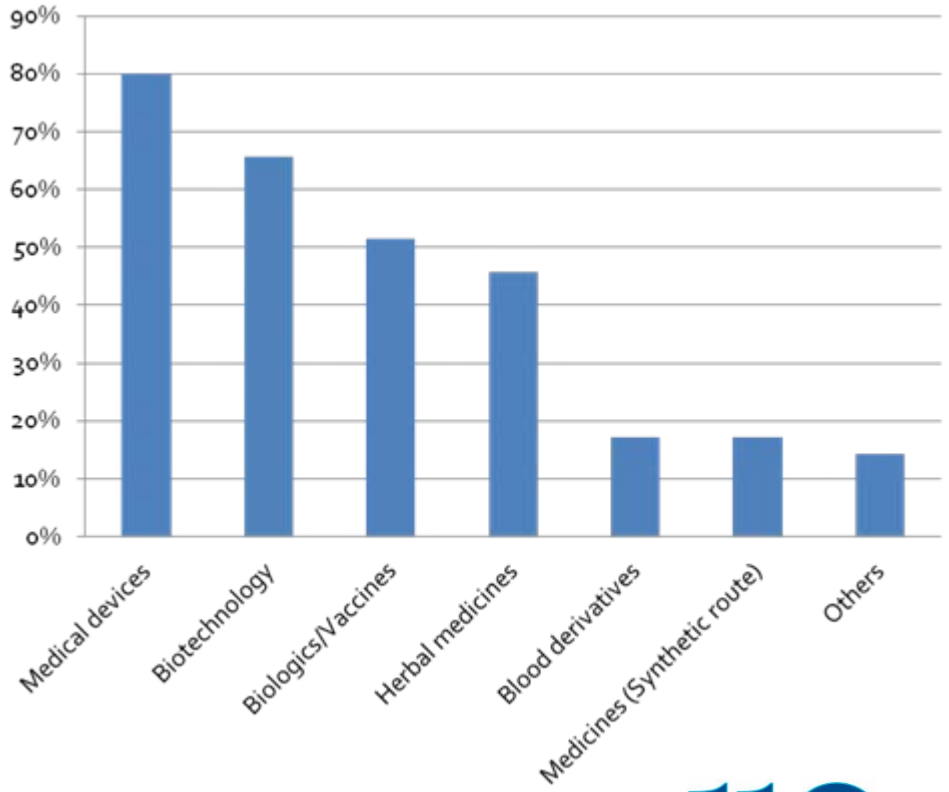


REGIONAL NRA PRIORITIES IN 2013 (I)

Survey response rate (results based on responses from 29 countries):
Yes 76%
No 24%

Part I: Identification of future national regulatory priorities/challenges for the work of PANDRH

National regulatory challenges identified by countries: Health Technologies



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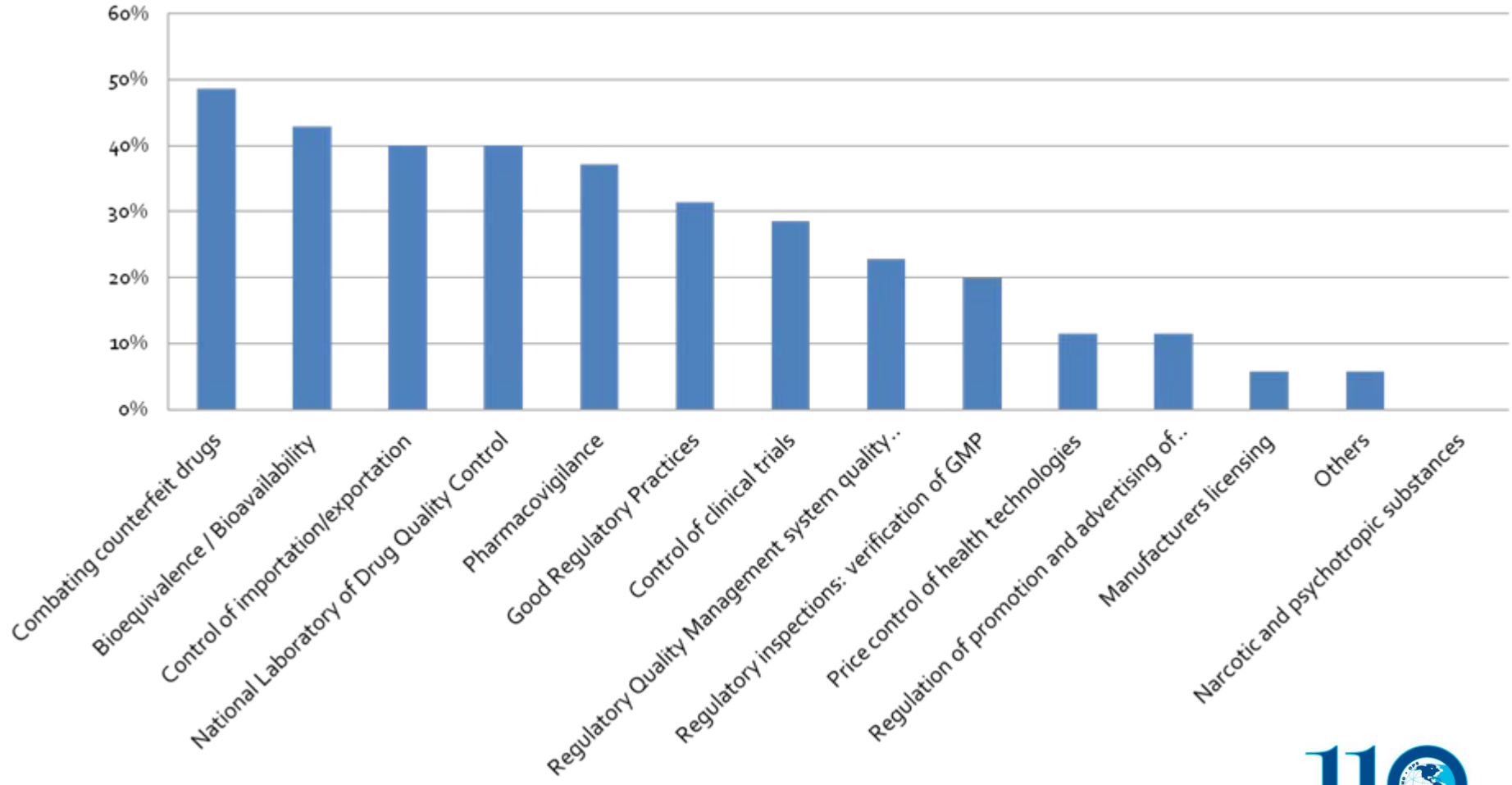
1902 - 2012

REGIONAL NRA PRIORITIES IN 2013 (II)

Part I (Cont.): National regulatory priorities/challenges identified by countries: Technical areas*



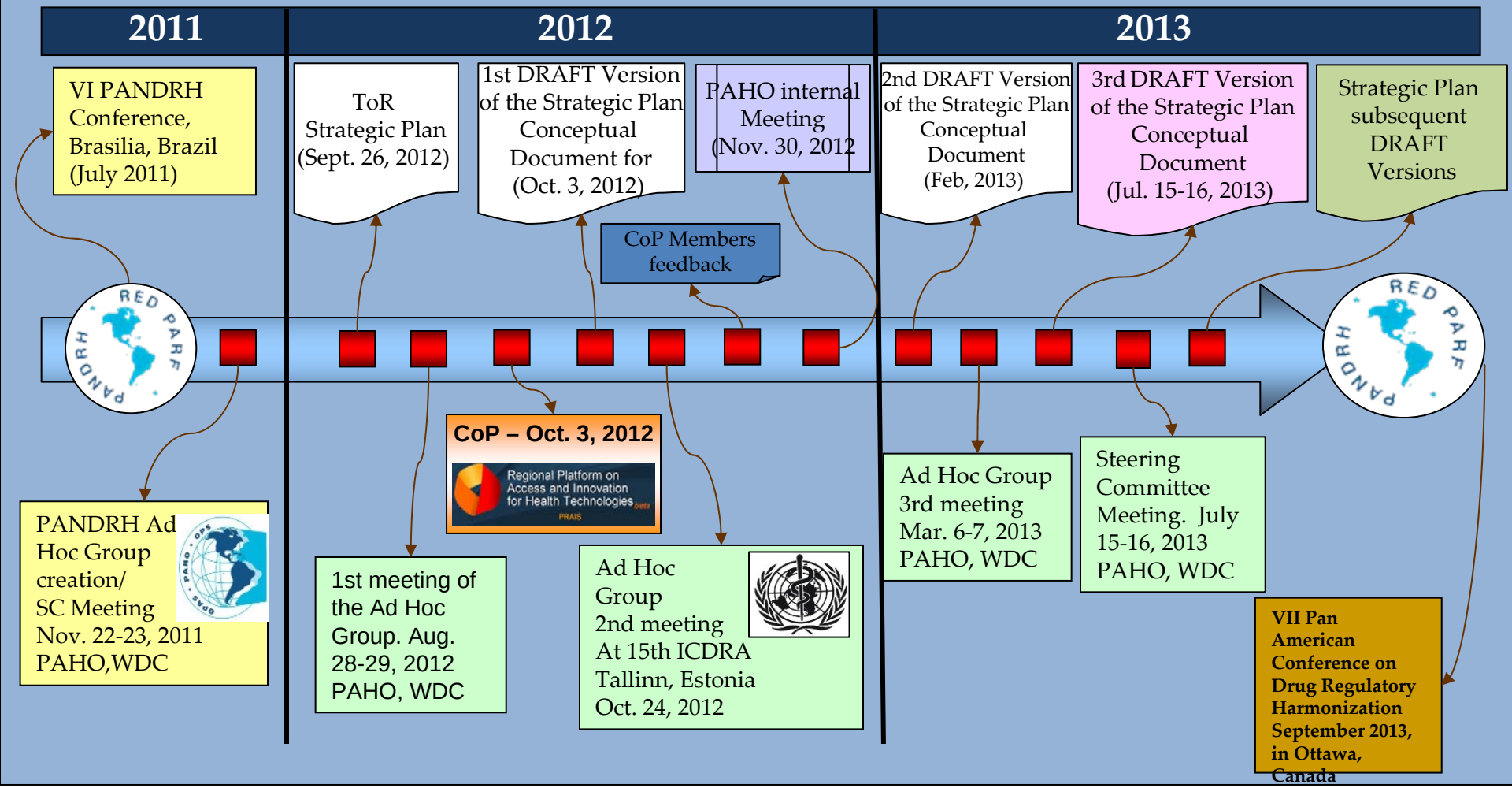
Source: PANDRH survey on current and future regulatory challenges in the Americas, 2013

1902 - 2012

CONSIDERATIONS FOR THE FUTURE OF PANDHR

- Approximately 60% of PANDRH technical documents have been used for the development of NRA regulations:
  - 34% have been fully adopted and 26% have been partially adopted
  - Of the remaining 40%, 55% correspond to countries that previously implemented other regulations and/or regulations were based on other harmonization initiatives
- Initial results from the studies and surveys facilitate:
  - identification of future priority areas for normative adoption / implementation (equivalency, SSFFC, biologicals, etc)
  - future focus areas for PANDHR to address current regulatory challenges
- Results to inform the PANDRH Strategic Development Plan 2014-2020

TIMELINE FOR THE PANDRH STRATEGIC PLAN 2014-2020



STRUCTURE OF THE STRATEGIC DEVELOPMENT PLAN 2014-2020

- Introduction and Context
  - Analysis of the situation in the Americas Region
  - Lessons learned
- Strategic Orientation
  - Purpose: To strengthen the capacity of National Regulatory Authorities (NRAs) in the Americas so support fulfillment of regulatory mandates efficiently, effectively, and transparently, through increased cooperation, moving towards regulatory convergence and harmonization
  - Four Strategic Objectives
    - Lines of actions
    - Expected results

COMPONENTS OF THE STRATEGIC DEVELOPMENT PLAN 2014-2020 (CONT.)

Strategic objectives (SO)

- 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 inside and outside PANDRH

VII PANDRH CONFERENCE: EXPECTED OUTCOMES

The PANDRH Steering Committee (PAHO Washington, July 2013) proposed expected outcomes from the VII PANDRH Conference are:

- Endorsement of the Strategic Development Plan 2014-2020;
- Discussion on how to approach and implement each of the strategic priorities;
- Agreement on the development of a joint implementation / work plan through the establishment of working groups that would address each of the four strategic objectives.

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