



CURRENT STATUS OF PAN AMERICAN NETWORK FOR DRUG REGULATORY HARMONIZATION (PANDRH):

Report to the ICH-GCG

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PANDRH: Pan American Network for Drug Regulatory Harmonization

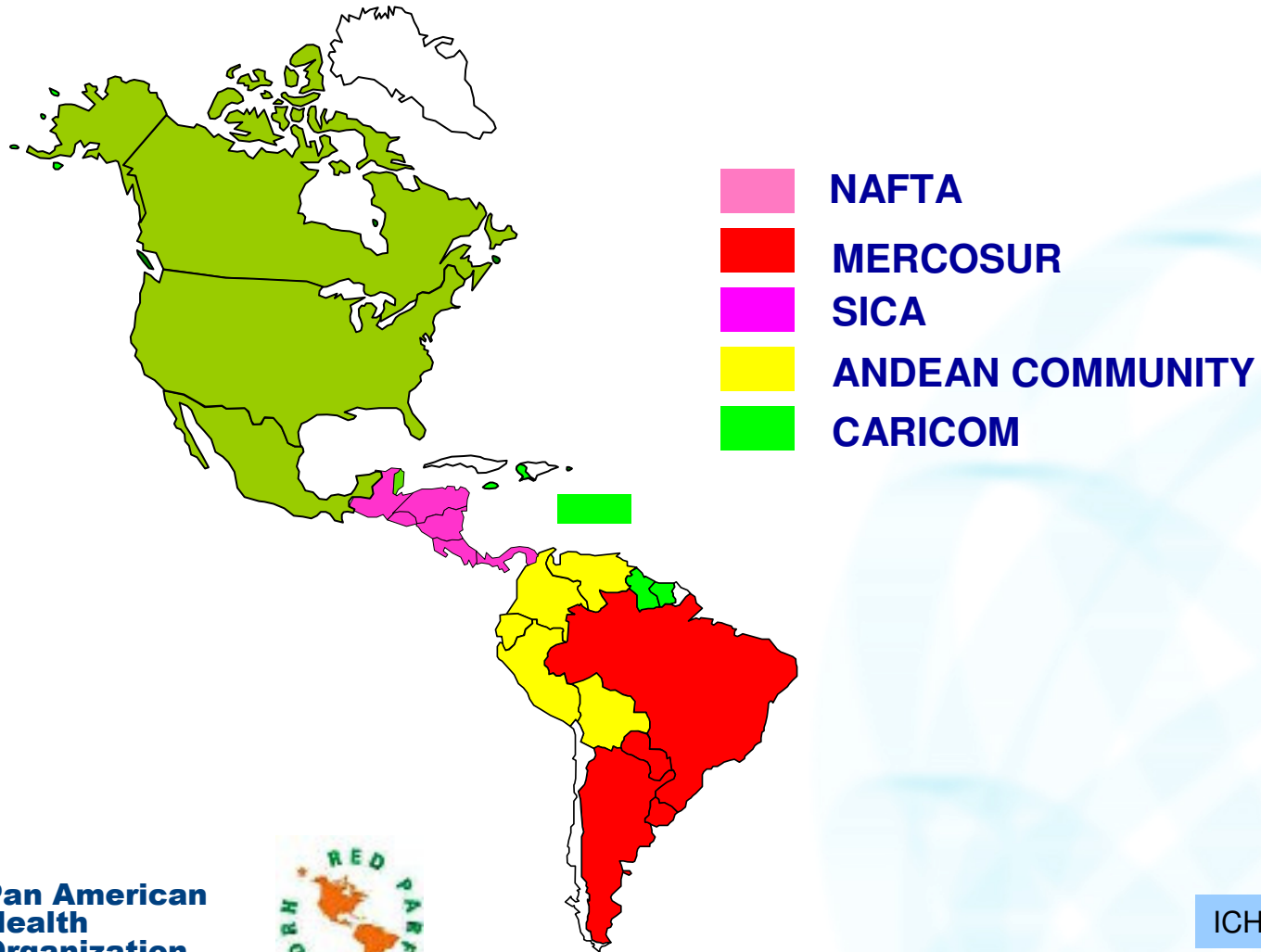
Establishes a Pan American Forum of Drug Regulatory Agencies (DRA) to discuss and search for solution of common problems, with DRAs leading and participating in the process. Focused on the discussion of main problems related to the harmonization of criteria in quality, safety and efficacy of drugs, consequently to the quality of pharmaceutical markets.

Working Groups

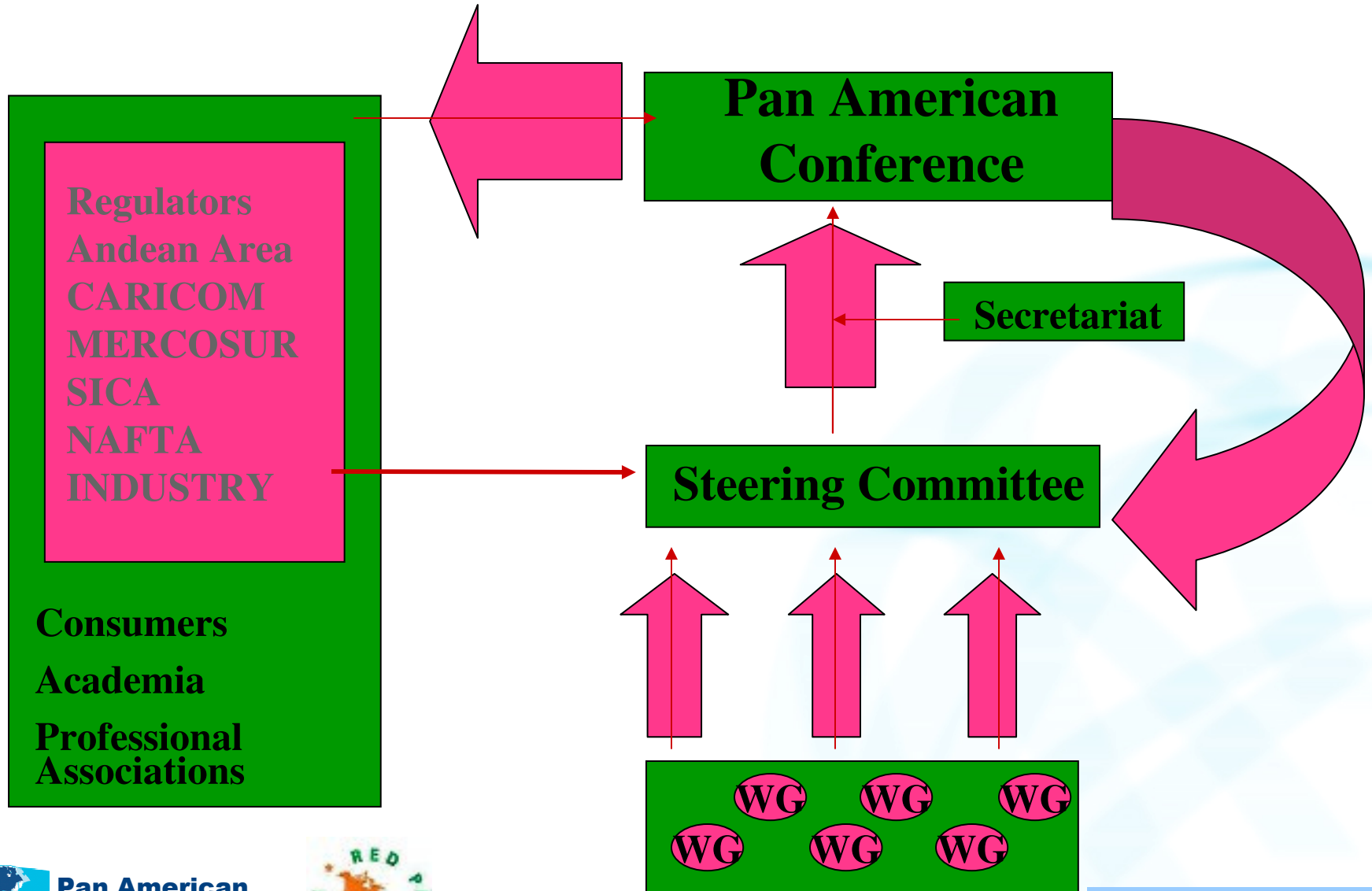
- **Good Manufacturing Practices**
- **Bioequivalence and Bioavailability**
- **Good Clinical Practices**
- **Drug Classification**
- **Counterfeit Drugs**
- **Good Laboratory Practices**
- **Pharmacopoeia**
- **Medicinal Plants**
- **Drug Registration**
- **Pharmacovigilance**
- **Vaccines**
- **Promotion and Marketing**



PANDRH Sub-regional Blocs



PANDRH Structure



V PANDRH Conference, Buenos Aires, 17-19 November 2008

- **>250 participants, NRAs, Industry, Academia:
including accredited PAHO/WHO NGOs, IOs and RHI**
- **Composed of Keynote Presentations, Panel
Presentations, WG Discussions, Conference meeting
and adoption of harmonized technical documents.**

Principle Themes of V Conference

- **Pharmaceutical Regulation and Public Health (PAHO/WHO and ANMAT Argentina)**
- **Update on Drug Regulatory Harmonization Initiatives**
 - ICDRA, ICH, PANDRH and ASEAN Initiatives
- **System for Inter-NRA Recognition**
 - Implement a transparent and uniform methodology for evaluating NRA performance to the establishment of NRAs of reference;
 - Initial participation of Latin American Regulators (7), now extended;
 - Tool for regulation of medicines (2007) based on WHO indicators for NRA assessment on vaccines (2004);
 - Consensus on tool and indicators, Mexico, July 2008 for implementation 2009;



Principle Themes of V Conference

- **Essential Functions in Medicines Regulation and Challenges for NRAs (PAHO/WHO)**
 - Presentation of core functions to include accountability and transparency
 - Challenges: mutual recognition system, off-label use, regulation of promotion and rational use, post-marketing controls
- **Counterfeiting as a Public Health Problem (WHO)**
 - Update on global and regional activities with discussion on definition.
- **WHO Prequalification (WHO)**
 - Presentation of scope, process and technical documentation
- **Rational Use as a Component in Regulatory Decisions (CC/PAHO)**
 - Regulation of information on use of medicines, monitoring of marketing of medicines

Principle Themes of V Conference

- **Panel discussion on Biotechnological and Biological Products**
 - PAHO/WHO, ALIFAR, FIFARMA, Health Canada.
- **Integrating PANDRH Recommendations into Sub-regional Integration Processes**
 - MERCOSUR (GMP), SICA, Andean, CARICOM
- **Results from PANDRH WGs:**
 - BE, PV, Vaccines, Drug Registration, GLP, Counterfeiting, GCP, Promotion, GMP.

Technical Documents Adopted (8)

- **BE: Framework for Implementation of Equivalence Requirements for Pharmaceutical Products***
- **PV: Good Pharmacovigilance Practices***
- **Vaccines: Harmonized Requirements for the Registration of Vaccines in the Region of the Americas and its guide of use**
- **GCP: Guide for conducting clinical studies in pediatric populations***
- **GMP: Decision tree for the Implementation of the Guidelines for Good Manufacturing Practices Inspection**
- **GMP: Good Manufacturing Practices for Pharmaceutical Ingredients (ICH-Q7)**
- **GMP: Code of Ethics for Inspectors of Good Manufacturing Practices**
** with changes suggested by the Conference*

Conclusions and Recommendations

- Issued to the Network, WGs, NRAs, Secretariat, Industry, Academia
- Some key examples:
 - BE, promotion of training for the use of the Technical Document
 - PV, implementation in two groups of countries, incorporate and position PV as a DRA activity
 - Vaccine: monitoring implementation of technical document
 - Registration: WG to review technical document on Harmonized Requirements for Drug Registration
 - Restructuring of WGs such as Drug Advertising, Medicinal Plants etc
- Secretariat to publish adopted Technical Documents
- Review of PANDHR Statutes to be completed by July 2009
- Reconstitution of Steering Committee
- Review participation of accredited NGOs in the Network



Steering Committee Meeting. July 2009. WDC

Conclusions:

- Finalisation of the PANDRH Statutes revision with consensus
- Proposal for the creation of virtual tools through the Secretariat to improve communication and document diffusion. Workshop for the presentation of these tools to be held in Panama, October 2009.
- Proposal for the creation of Biotechnology Products Working Group (Biosimilars)
- NGO participation in the Conference confirmed, limited for WG

Recent Advances

Creation of portfolio of experts for the Evaluation of NRAs, with the participation of member of NRAs from most of the contries.

Evaluation of three NRAs:

- Chile
- Cuba
- Colombia
- Argentina will be evaluated in December 2009
Using the indicators approved by the Network members in July 2008

Next Steps

- December 2010. PANDHR Steering Committee Virtual Meeting
- February 2010 PANDRH Steering Committee to review:
 - Reports from WG.
 - Finance resources supporting the Network
- Publication and Implementation of V Conference Recommendations, including publication of Technical Documents
- Restructure of WG and plans definition
- Regulators meeting facing the H1N1 pandemic, Dec 1-3,2009)

Contact and Further Information

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- **Link**
http://new.paho.org/hq/index.php?option=com_content&task=blogcategory&id=1156&Itemid=513