

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

Report to the ICH-GCG

James Fitzgerald PhD

Senior Advisor Essential Medicines and Biologicals

PANDRH Secretariat

PAHO/WHO Washington DC



ICH-GCG June 2009

PANDRH: Pan American Network for Drug Regulatory Harmonization

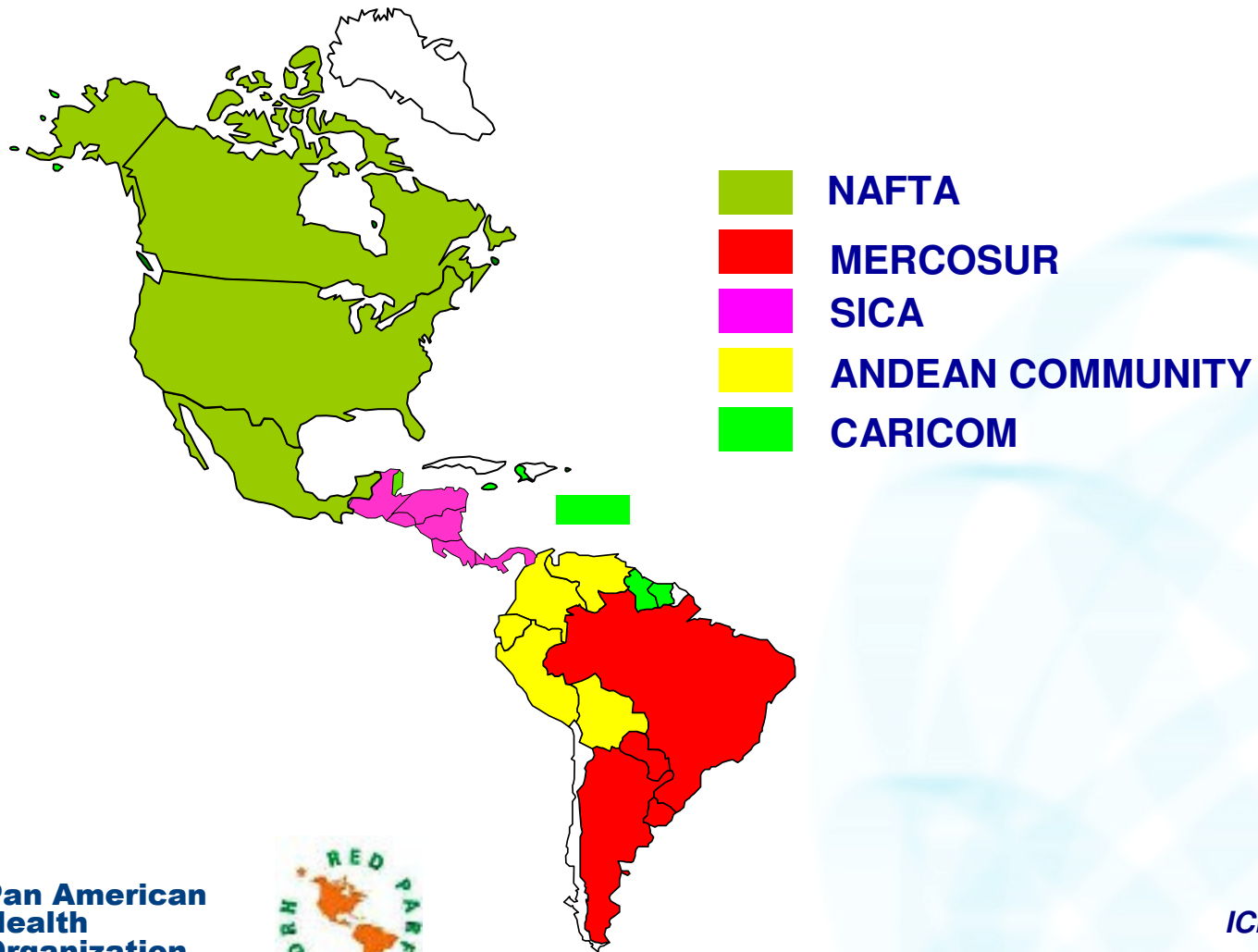
1. Establishes a Pan American Forum of Drug Regulatory Agencies (DRA) to discuss and search for solution of common problems, with DRAs leading and participating in the process.
2. Strengthens the establishment of priorities in drug regulatory harmonization processes and encourage convergence of drug regulatory systems in Region.
3. Improves access to quality, safety & efficacy drugs to improve quality of pharmaceutical markets.
4. Promotes technical cooperation where more developed DRA share knowledge and experiences with less advanced DRA

Working Groups

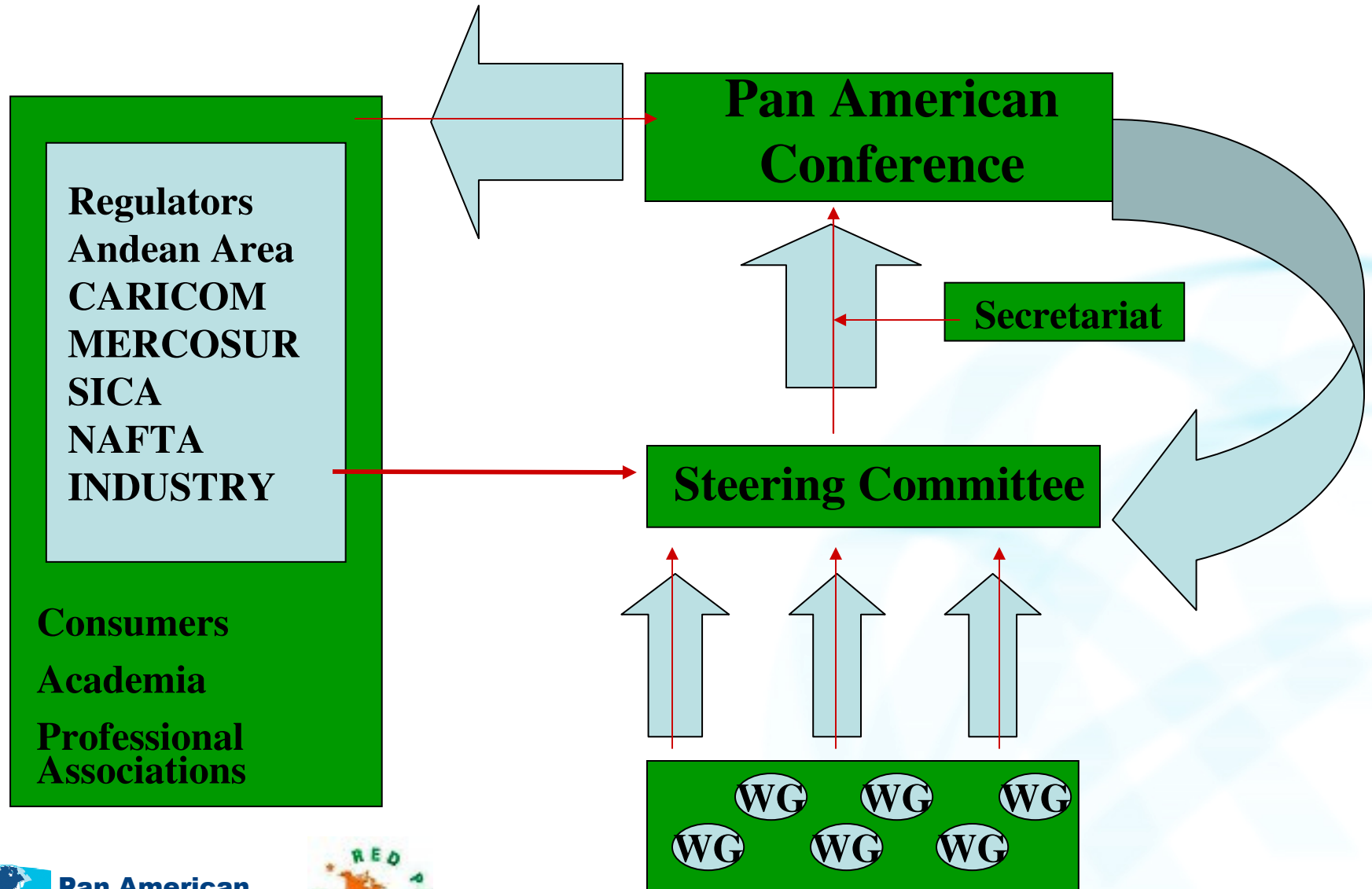
- Good Manufacturing Practices
- Bioequivalence and Bioavailability
- Good Clinical Practices
- Drug Classification
- Counterfeit Drugs
- Good Laboratory Practices
- Pharmacopoeia
- Medicinal Plants
- Drug Registration
- Pharmacovigilance
- Vaccines
- Promotion and Marketing

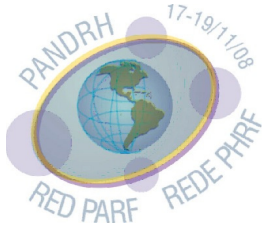


PANDRH Sub-regional Blocs



PANDRH Structure

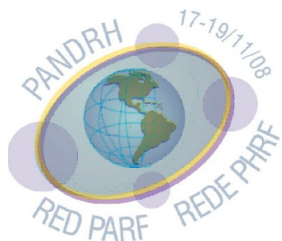




V PANDRH Conference, Buenos Aires, 17-19 November 2008

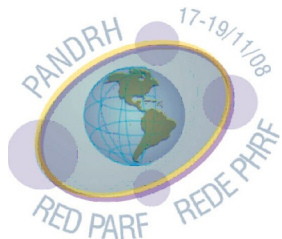
- **Presentation and Introduction by Director PAHO/WHO, Americas and Director of ANMAT, Argentina**
- **>250 participants, NRAs, Industry, Academia: including accredited PAHO/WHO NGOs, IOs and HIs**
- **Composed of Keynote Presentations, Panel Presentations, WG Discussions, Conference meeting and adoption of harmonized technical documents.**





Principle Themes of V Conference

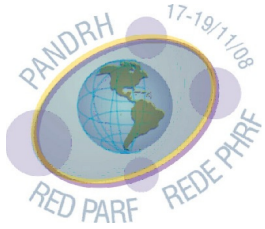
- **Pharmaceutical Regulation and Public Health (PAHO/WHO and ANMAT Argentina)**
- **Update on Drug Regulatory Harmonization Initiatives**
 - ICDRA, ICH, PANDRH and ASEAN Initiatives
- **System for Inter-NRA Recognition (PAHO/WHO & CECMED (Cuba))**
 - Establish a transparent and uniform methodology for evaluating NRA performance;
 - Initial participation of Latin American Regulators (7), now extended;
 - Tool for regulation of medicines (2007) based on vaccine assessment (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

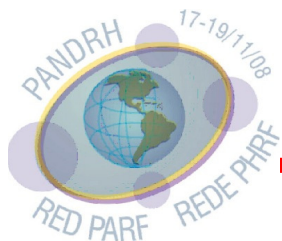




Principle Themes of V Conference

- **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.





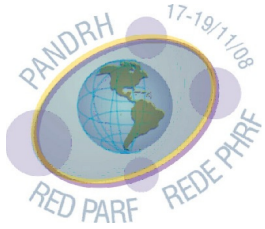
Technical Documents Adopted (8)

- **BE: Framework for Implementation of Equivalence Requirements for Pharmaceutical Products***
- **PV: Good Pharmacovigilance Practices***
- **Vaccines: Harmonized Requirements for the Registration of Vaccines in the Regional of the Americas**
- **Vaccines: Guidelines for Preparation of a request for registration.**
- **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*



ICH-GCG June 2009



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

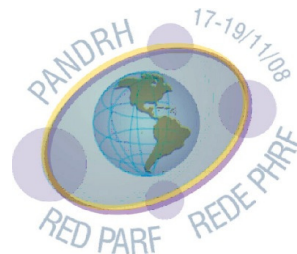


Next Steps

- **July 2009, PANDHR Steering Committee Meeting, PAHO Washington DC**
 - Adoption of revised Statutes
 - Renewal of WG Membership
 - Consideration of accredited NGO participation in the Network
- **Implementation of V Conference Recommendations, including publication of Technical Documents**
- **Strengthening Secretarial Support to the Network**
 - Dr. Jose Daniel Pena, PAHO/WHO.

Contact and Further Information

- Contact: James Fitzgerald, fitzgerj@paho.org
- Link
http://new.paho.org/hq/index.php?option=com_content&task=blogcategory&id=1156&Itemid=513



ICH-GCG June 2009