

Pan American Network on Drug Regulatory Harmonization (PANDRH)

Report to GCG-ICH Oct. 2007
Secretariat: PAHO/WHO

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Background and Structure

- Regional Harmonization Initiative started in 11/1997 during the I Pan American Conference on Drug Regulatory Harmonization.
- PANDRH was officially established in 11/1999 during the II Conference.
- Participation:
 - DRAs from 35 PAHO Member States;
 - Regional Associations of Pharmaceutical Industry (FIFARMA & ALIFAR);
 - Academia
 - NGO's



Groups of Economic Integration in the Region of the Americas



- NAFTA (1994)
- MERCOSUR (1991)
- SICA (1961)
- ANDEAN COMMUNITY (1969)
- CARICOM (1973)

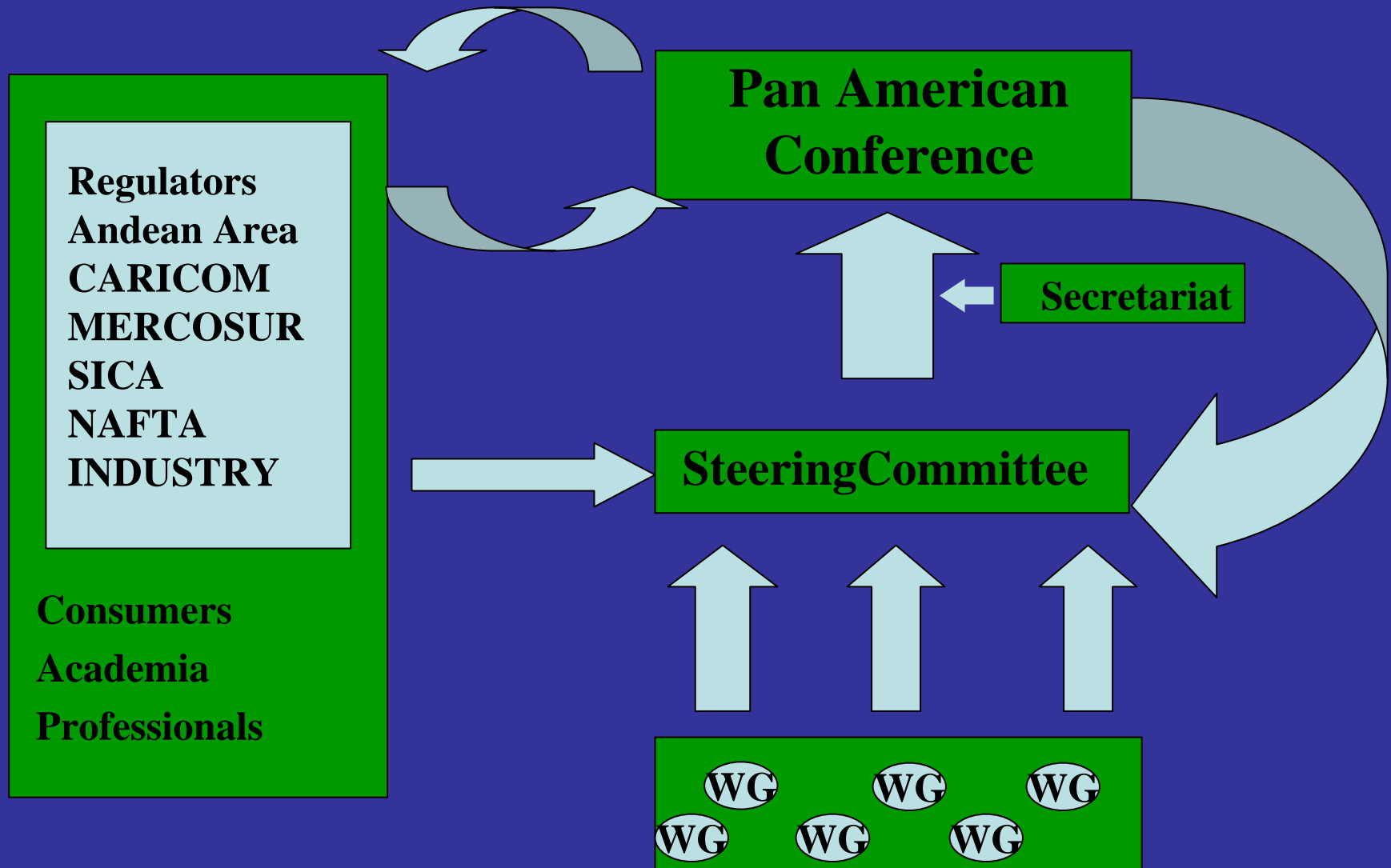
- Bilateral & Multilateral cooperation agreements;
- Free Trade agreements;
- ALADI: LA Association for Integration (12 countries, 1980)



Operational Components

- Pan American Conferences
- Steering Committee
- Working Groups
- Secretariat

PANDRH Operational Framework



Steering Committee 2005 - 2007

NRA

NA:

CA:

CR:

ME:

AA:

Members

Mexico

Costa Rica

Trinidad & Tobago

Argentina

Colombia

Alternate

USA

Panama

Barbados

Chile

Bolivia

Pharmaceutical Industry

One rep from FIFARMA

One rep from ALIFAR

PANDH Working Groups

1. GMP (FDA/USA)
2. BE (FDA/USA)
3. GCP
(ANMAT/Argentina)
4. D. Counterfeiting
(ANVISA/Brazil)
5. D. Classification
(MOH/GUATEMALA)
6. Drug Approval
(Registration MOH/
Venezuela)
7. Pharmacopoeia (USP,
USA)
8. Medicinal Plants
(MOH JAM)
9. Pharmacovigilance
(INVIMA COL)
10. GLP (ISP/Chile)
11. Drug Promotion
(ANVISA/Brazil)
12. Vaccines (MOH/Cuba)

Technical Documents and Guides approved by PANDRH

- Regional Guidelines for GMP Inspections
- Good Clinical Practices: document for the Americas
- Criteria to classify OTC drugs
- Label and Patient Information for OTC Medicines
- Proposed Structure for NRA to Combat Drug Counterfeiting
- Roadmap to strengthen Combat Drug Counterfeiting

Draft Technical Documents Under Public Review

1. Decision tree for Implementing GMP Guideline and WHO Report 32
2. Code of Ethics
3. GMP for Active Pharmaceutical Ingredients (ICH GUIDE)
4. Regional Strategy for implementing BE studies based upon the product' health risks
5. Decision Tree to implement BE studies
6. Common requirements for Vaccine registration
7. Evaluation tool for Quality Control Laboratories (final draft being tested in Jamaica and Dominican Republic)

Regional Studies and Special Tasks

- **Update of PAHO publication Glossary of Terms (ad-hoc group)**
- **Regional Studies:**
 - **Current situation of Pharmacovigilance in the Americas**
 - **Follow up regional study on Drug Counterfeiting in the Americas**

PANDRH' WGs Regular Activities

- 1. Follow up and direct support to countries for implementation of approved guides**
- 2. External Quality Control Program**
- 3. National Seminars: GCP, BE**
- 4. Educational programs**

PANDRH Support to Training (2006-2007)

DEVELOPED

- GMP (Basic & Validation (WHO))
- GMP (FDA))
- GMP PANDRH Guideline Implementation
- GCP for NRA (PANDRH/ GCP: doc of the Americas)
- BE (Basic & In vitro method (FDA))
- HPLC Practical Application
- GLP

IN PROCESS

- Combat drug counterfeiting (Drafted by ANVISA)
- Drug Registration/ NRA Basic Functions (based on WHO)
- BE Training Seminar (Module 2 & 3 including data analysis)
- Pharmacovigilance training modules



PANDRH Internal challenges: SC Meeting Argentina, Oct 2007.

Challenges

1. PANDRH, roles and functions better defined;
2. PANDRH WG operation should be improved;
3. Lines of authority among PANDRH component should be clarified and strengthened (Conference, SC and WGs)
4. Short and long term financing must be addressed and resolved;
5. Communication at conferences should be clarified

Guiding Principles in Addressing Challenges

1. Effective DRA Representation, Participation
2. Complementarity with DRA functions
3. Utility of products
4. Practicality in defining scope of work, operational Capacity
5. Sustainability / Financing
6. Inter-country cooperation



Next Steps

1. Organization of III Pan American Conference, Buenos Aires, November 2008
2. Steering Committee Meeting 2008 to:
 1. Support organization of III Conference
 2. Address PANDHR Challenges including Review of Statutes and WG Scope / Operations
3. Address WG Priorities:
 1. Meetings of Drug Registration and Drug Counterfeiting WGs
 2. Training Implementation and sustainability
 3. Communication and reporting between WGs and the SC
 4. Inter-relation between WG (e.g. Registration and GMP)



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Medicamentos Esenciales, Vacunas y Tecnologías de Salud

RED PANAMERICANA PARA LA ARMONIZACIÓN DE LA REGLAMENTACIÓN FARMACÉUTICA (RED PARE)

DIRECTORIO DE AUTORIDADES NACIONALES REGULADORAS DE LAS AMERICAS	Directorio de Autoridades Nacionales Reguladoras de las Américas - Inglés - Reunión SubRegional-Agosto 2005 Autoridades Reguladoras de Centroamerica Cuba y Rep. Dominicana
RESOLUCIÓN OPS/OMS ARMONIZACIÓN REGLAMENTACION FARMACÉUTICA	Documento CD42/13: Armonización de la reglamentación

Se presentan los documentos que apoyan el desarrollo de la Red Panamericana para la

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