

PAN AMERICAN NETWORK ON DRUG REGULATORY HARMONIZATION (PANDRH)

Report to GCG-ICH
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PANDRH

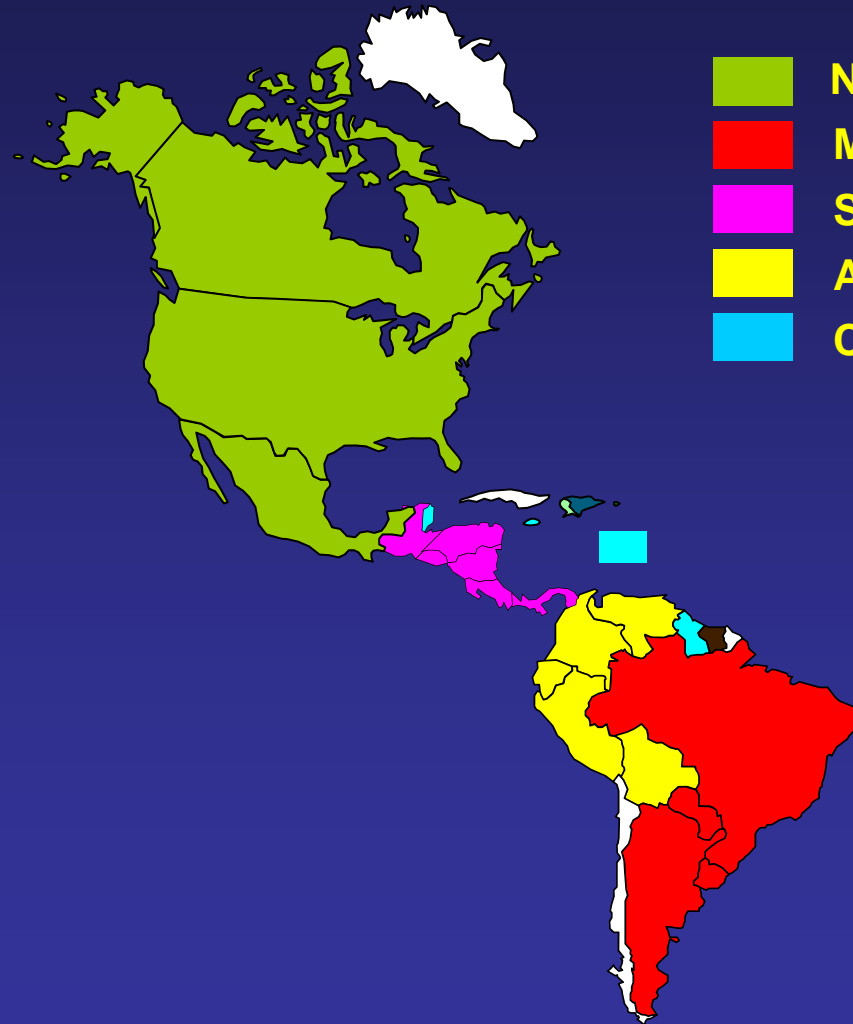
- Regional harmonization initiative started in 11/1997 with the I Pan American Conference on Drug Regulatory Harmonization.
- PANDRH was officially established in 11/1999 during the II Conference.

PANDRH:

- DRAs of 35 PAHO Member States;
- Representatives of 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 agreements;
- Free Trade agreements;
- ALADI: Asociacion Latinoamericana de Integracion (12 countries, 1980)



Components

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

Activities

Nov 2006 - May 2007

- **Meetings**
 - WG Bioequivalence (COR, 11/06)
 - WG Combating Drug Counterfeiting (ARG, 11/06)
 - WG Good Laboratory Practices (BOL, 11/06; GUT, 05/07)
- **Educational Seminars**
 - GMP(MEX, COR, PER)
 - GLP (HON, VEN, BOL, CHI)
- **Other related activities**
 - Implementation of GLP Guidelines (BOL, HON, JAM, VEN, GUT)
 - EQCP (6th test to 21 laboratories)



Review of PANDRH internal challenges

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

- 1. Project: Improving Drug Quality through Drug Regulatory Harmonization**
- 2. Rules & Regulation under review**
- 3. Ad-hoc committee to propose a methodology for next Conference**



Review of PANDRH external challenges

1. Strengthen support and acceptance of PANDRH by high political level (MOH) by including PANDRH in national and regional pharmaceutical political agenda.
2. Improve effective participation of countries: DRA and other sectors of drug regulation.
3. Promote acceptance of PANDRH products at national and sub-regional level.
4. Improve communication among stakeholders mainly at country level and between regulators and regulated sectors.
5. Implementation not necessary role of PANDRH, other actors and strategies.



Categories of WG Members

- **Main Member:** represents a DRA in each of the 5 sub-regional integration Groups and the two industry (decision-makers)
- **Altern:** Represents one DRA of the same sub-region but different country
- **Resource Person:** experts invited to participate at WG meetings
- **Observer:** Generally designated by DRA
- **Focal Point:** from DRA of countries not represented in the WG
- **Substitute:** member to attend WG meetings when the main member is unable to attend. It applies to industry representative.



PANDRH process for developing harmonized docs

- **Phase 1: Preparation of a draft**
 - Preparation of first draft by one or more WG member
 - Discussion by WG and GTD
- **Phase 2: Draft for Public Opinion**
 - Web consultation
 - Consolidation of comments
- **Phase 3: Preparation of Final draft**
 - Review of comments and by WG
- **Phase 4: Approval/Adoption by Conference**
 - Information/Authorization by SC
 - Presentation and Approval by Conference
- **Phase 5: Implementation**
 - Dissemination & Education
 - Adoption (national & Sub-regional)
 - Legislation (if necessary)
 - Follow up and Evaluation



WG proposal preparation requires to review:

1. WHO policy and available technical doc & guides
2. ICH existing docs
3. Regional and/or subregional guides (MERCOSUR, AA, Central America, NAFTA, CARICOM)
4. National documents from countries in the Region (FDA, ANMAT, ANVISA, Canada, etc)
5. Regional or National documents from outside the Region (EMA, Australia,...)



PANDRH PROPOSAL



Training Seminars

1. **Good Manufacturing Practices:**
 1. *WHO Basic and WHO Validation*
 2. *Appropriate use of PANDRH guideline for GMP insp*
2. **Good Laboratory Practices (PANDRH)**
 1. *WHO documents*
 2. *Autoevaluation guidelines*
3. **Good Clinical Practices: doc of the Americas (PANDRH)**
4. **Bioequivalence: Statistic evaluation (under development by WG/BE)**
 1. *Seminars associated to WG meetings*
5. **Basic Functions of DRA: based on WHO docs (under development)**
6. **Combating Drug Counterfeiting (in preparation by ANVISA)**
7. **Good Pharmacovigilance Practices (under development by WG/Ph)**

http://www.paho.org/english/ad/ths/
ev/RedParf-home.htm

The screenshot shows a Microsoft Internet Explorer browser window with the address bar displaying the URL: <http://www.paho.org/spanish/ad/ths/ev/RedParf-home.htm>. The browser's menu bar includes File, Edit, View, Favorites, Tools, and Help. The address bar contains the URL and a search box. Below the address bar, there are several toolbars, including My Web Search, ThomasNet, and various utility buttons like Mail, My Yahoo!, and Answers. The main content area displays the website for the Organización Panamericana de la Salud (Pan American Health Organization). The page header includes the organization's logo and name, along with a search bar and a link to view the page in English. The navigation menu consists of several tabs: Página Inicial, Datos de salud pública, Lista de Temas, Centro de prensa, Productos de información, Editorial OPS, and Recursos de conocimiento. The main content area features a section titled "Medicamentos Esenciales, Vacunas y Tecnologías de Salud" and a sub-section for the "RED PANAMERICANA PARA LA ARMONIZACIÓN DE LA REGLAMENTACIÓN FARMACÉUTICA (RED PARF)". Below this, there are several links and text blocks, including "DIRECTORIO DE AUTORIDADES NACIONALES REGULADORAS DE LAS AMERICAS", "RESOLUCIÓN OPS/OMS ARMONIZACIÓN REGLAMENTACION FARMACÉUTICA", and "Documento CD42/13: Armonización de la reglamentación". The browser's taskbar at the bottom shows the Start button, several open applications, and the system clock displaying 2:04 PM.



Thank You