

PAN AMERICAN NETWORK ON DRUG REGULATORY HARMONIZATION (PANDRH)

Report to ICH
From June to
October 2006



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PAHO/WHO



PANDRH

Regional harmonization initiative started in November 1997 with the I Pan American Conference on Drug Regulatory Harmonization, and PANDRH was officially established in Nov 1999 during the II Conference.

DRAs of 35 PAHO Member States and Representatives of FIFARMA & ALIFAR as Regional Associations of Pharmaceutical industry in the American Region



Components

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

Activities June-October 2006

- **Meetings**

- Steering Committee (V meeting/June)
- Pharmacovigilance WG (First meeting) (Aug)
- Drug Promotion WG (First meeting) (Aug)

- **Educational Seminars**

- GMP(URU, CHI, COL, ECU, VEN, PAN)
- GLP (DOR, CHI)
- GCP (CHI)

- **Other related activities**

- DRA Caribbean Sub-region (Sep)
- PANDRH presentation at the EAMI Biannual meeting (Oct)



SC approved: Review of PANDRH Strategic document: Strengthens

1. Inclusive of all DRA in the American Region
2. Based on Panamericanism
3. All main stakeholders participate in the process
4. Governance model: inclusive and transparent
5. Relationship with international drug regulatory harmonization initiatives: GCG/ICH, IRCH
6. WG members are professionals members of DRA offices, pharmaceutical industry and academia who are responsible for applying, enforcing and training on the PANDRH agreements.



SC approved: Review of PANDRH Strategic document: Challenges (internally)

1. Short and long term financing must be addressed and resolved
2. PANDRH WG operation should be improved
3. Lines of authority among PANDRH component should be clarified and strengthened (Conference, SC and WGs)
4. 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**



SC approved: Review of PANDRH Strategic document: Challenges (externally)

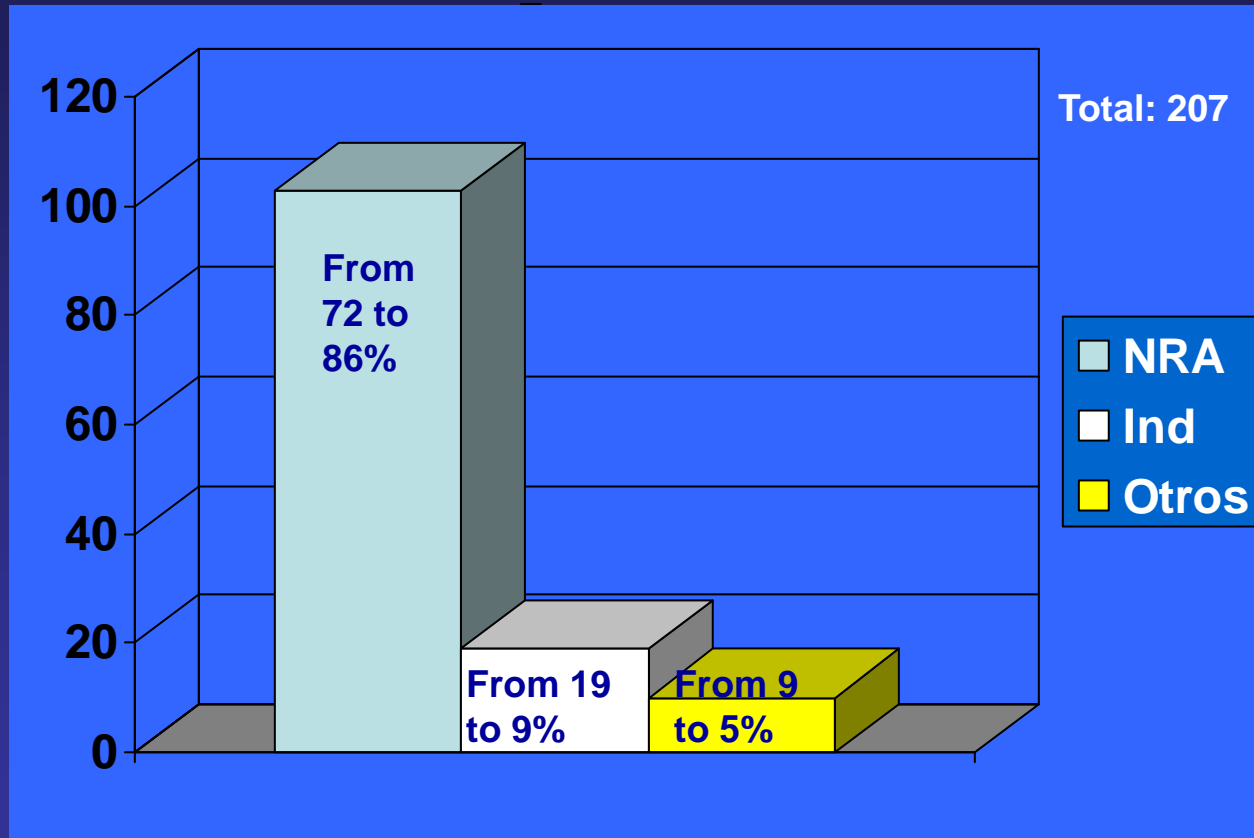
1. Strengthen support and acceptance of PANDRH initiative by high political level (MOH) by including PANDRH in national and regional pharmaceutical political agenda.
2. Improve effective participation of countries: DRA and other sectors of drug regulation.
3. Promote acceptance of PANDRH products at national and sub-regional level.
4. Improve communication among stakeholders mainly at country level and between regulators and regulated sectors.



SC approved: Categories of 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.

SC approved: Group of Technical Discussion extended to NFP





SC approved: 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



Technical documents/Guides by phase

Phase 1: Preparing Drafts	15
Phase 2: Public Opinion	7
Phase 3: Final draft	-
Phase 4: Approved by PANDRH	7
Phase 5: Implementation	7



WG proposal preparation requires to review:

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



PANDRH PROPOSAL



New WGs Priority tasks

- **Pharmacovigilance**

1. Pharmacovigilance and Public Health
2. Evaluation of existing data base
3. Educational seminar on Pharmacovigilance
4. Good Pharmacovigilance Practices

- **Drug Promotion**

1. Criteria and methodology to evaluate drug promotion
2. Data base on drug Promotion
3. Evaluation of impact of regulatory decisions on DP



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)**
3. **Good Clinical Practices: doc of the Americas (PANDRH)**
4. **Bioequivalence: Statistic evaluation (under development by WG/BE)**
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)**



Plan of Training Seminars 06-07: Level of implementation

- Total: 40

– Implemented :	14	35%
– Organized:	13	33 %
– To Be Confirmed:	13	33 %



Programmed Activities Nov –Dec 2006

- **Meetings:**
 - GCP WG (VI meeting) (Nov)
 - BE (VIII meeting) (Nov)
 - Combat Drug Counterfeiting (IV meeting) (Nov)
- **Educational Seminars**
 - GMP(DOR, PER & COR)
 - GLP (BOL)

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RESOLUCIÓN OPS/OMS ARMONIZACIÓN REGLAMENTACION FARMACÉUTICA

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

[Documento CD42/13: Armonización de la reglamentación](#)

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**Muchas gracias
Muito obrigada
Thank You
Merci**