



Pan American Network on Drug Regulatory Harmonization (PANDRH)

REPORT TO ICH
June 2006
Secretariat: PAHO/WHO



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

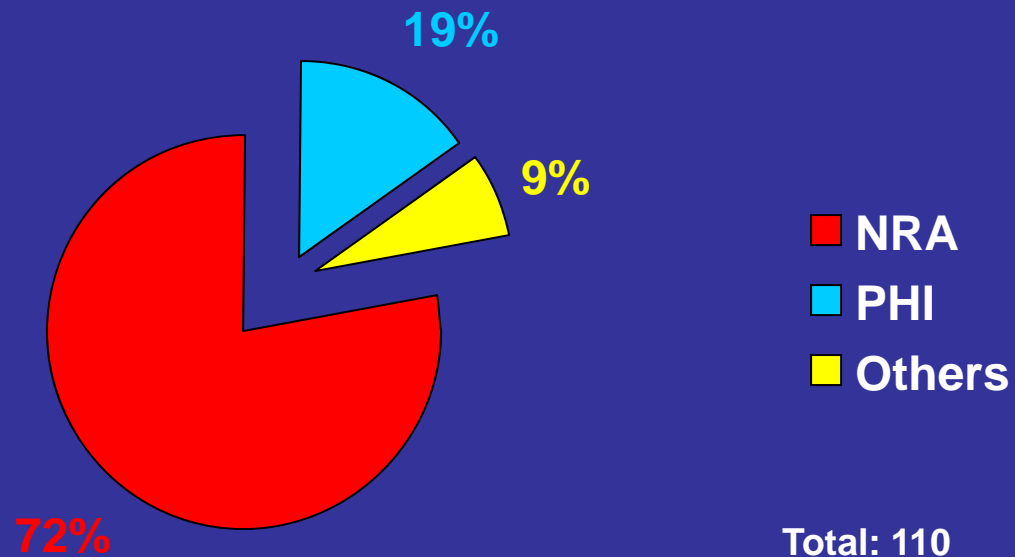
One rep from ALIFAR

PANDH Working Groups

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



Professionals by Organizations



Total: 110

Members

Process for developing PANDRH proposals

- **Phase 1: Development of a draft**
 - draft developed (by one or two members)
 - Discussion by all members of the WG
- **Phase 2: Draft ready for public opinion**
 - Web page consultation
 - Consolidation of comments
- **Phase 3: Final draft prepared**
 - Review of comments and decision by the WG
- **Phase 4: Approval by PANDRH Conference**
 - Information to the SC
 - Presentation at the Conference

Technical Documents and Guides approved by PANDRH (phase 4)

- **Regional Guideline for GMP Inspection**
- **Good Clinical Practices: document of the Americas**
- **Criteria to classify OTC drugs**
- **Label and Prospect Information for OTC**
- **Proposed Structure for NRA to Combat Drug Counterfeiting**
- **Roadmap to strengthen combat drug counterfeiting**

Draft Technical Documents and Guides developed by WG: public Opinion (Phase 2)

1. Decision tree for Implementing GMP Guideline and WHO Report 32
2. Code of Ethic
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)

Technical Documents and Guides being developed by WGs. Phase 1 (i)

1. Propose structure for National Regulatory Authorities to lead GMP implementation
2. Review of National Legislation to implement WHO Report 32 and PANDRH Regional Guideline on GMP
3. Regional proposal on Common requirements for Drug Registration
4. Pharmacological Norms
5. Guideline for NRA Assessment
6. Guideline for Pediatric studies

Technical Documents and Guides being developed by WGs Phase 1(ii)

7. Categorization of Medicinal Plants in the America
8. Harmonization of monograph content for Medicinal Plants
9. GMP for medicinal plants products
10. Label for Herbal medicines and for Dietary medicines (jointly Drug Classification and Medicinal Plants WGs)
11. List of product to be classify as OTC drugs
12. Follow up in research of new vaccines
13. GMP for vaccines production
14. Norms & procedures for EQCP

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 (2005)

DEVELOPED

- GMP (Basic & Validation (WHO))
- GMP (FDA))
- BE (Basic & In vitro method (FDA))
- HPLC Practical Application

IN PROCESS

- GMP Guideline Implementation
- Combat drug counterfeiting
- GCP for NRA
- GLP
- Drug Registration/ Evaluation of dossiers
- BE Module 2 & 3 (in vivo & data analysis)

PANDRH Support to Training (2006)

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)



PANDRH' Financial Sources



Conference (biannual): Pharmaceutical industry associations (FIFARMA & ALIFAR); Governments; and PAHO funds (regular and extra-budgetary)

Working Groups Meetings: Governments, Industry (their representative at the meetings); NGOs, PAHO Regular and extra-budgetary funds

Educational Activities: Registration fees; PAHO Regular and extra-budgetary funds

General Operation (Secretariat, Logistics, Webpage, Communication system, etc.): PAHO Regular and extra-budgetary funds

Project: Improving Drug Quality through Drug Regulatory Harmonization. Developed by PAHO and supported by NRAs

PANDRH web page

<http://www.paho.org/medicamentos-esenciales>

<http://www.paho.org/Essential-Medicines>

Muchas Gracias

Thank You