



Pan American Network for Drug Regulatory Harmonization (PANDRH)

GCG/ICH
Chicago, November
2005

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PAHO/WHO

Update on PANDRH Working Groups

- **GMP**

- Implementation Pilot educational seminar on Use of the Regional Guideline for GMP inspections and implementation in 19 LA countries
- Decision Tree for the Application of the Regional Guide
- Strategies for GMP management by NDRA in the Americas
- Mutual recognition of GMP Inspections
- Guideline API (ICH, MERCOSUR, etc.)
- Standard of Conduct

Update on PANDRH Working Groups

- **Registration:**
 - Countries (CA) are comparing national regulation and PANDRH proposal on Common requirements for drug registration: Central America economic integration group (UA), Panama, Costa Rica and Cuba
 - Pharmacological Norms: Up date
 - Electronic System for drug Registration (SIAMED)
- **Good Clinical Practice**
 - WG continue the development of Guide for GCP in Pediatric population
- **Vaccines**
 - Common requirements for registration

Update on PANDRH Working Groups

- **BE**

- Scientific criteria: Complement WHO document on specific aspects of regional interest
- Updating comparative study on BE implementation of BE for the methodology to advance and harmonize developing of the regional strategy
- Implementation: dissemination in Peru and Uruguay
- National University of Costa Rica and NRA is organizing BE educational seminar for Central American countries

Update on PANDRH Working Groups

- **Pharmacovigilance**
 - Regional study in the Americas

- **Medicinal Plants**
 - WHO working group on International Regulatory cooperation on herbal medicines (Nov 2005, Ottawa Canada)

- **GLP**
 - Educational modules on GLP
 - Norms and procedures for the EQCP
 - Implementation of the sixth round (TB product)

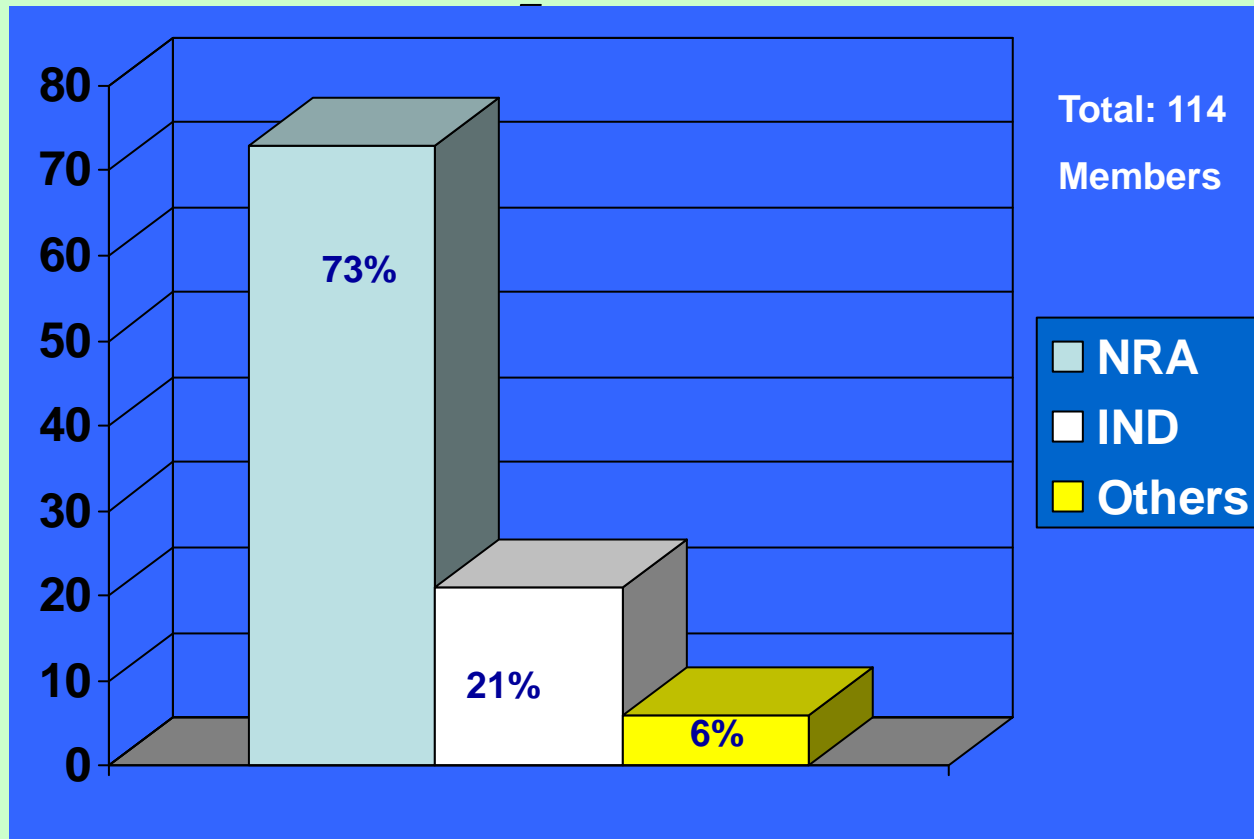
Update on PANDRH Secretariat

- Following up WGs meetings, tasks and studies
- Implementation planning with NRA: CA ready; pending Su
- Preparation of project proposal for PANDRH with the Steering Committee & NRA: First draft ready
- Glossary of terms: establishing the ad-hoc group
- Up date web page

Grupos de Trabajo de la Red PARF

1. BPM
2. BE
3. BPC
4. Falsificación
5. Clasificación
6. Registro
7. Farmacopeas
8. Plantas Medicinales
9. Farmacovigilancia
10. Vacunas
11. BPL
12. Promoción de Medicamentos

WG' Members by Organizations



WEB PAGE

Spanish:

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

English:

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

Muchas gracias

Thank You