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Pan American Network on Drug Regulatory Harmonization:
PANDRH overview / Future perspectives

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PANDRH overview: recent development / challenges

Content

• Background

• Update of current activities in the Americas Region regarding harmonization:
  – Recent adopted documents
  – PANDRH and NRAs strengthening
  – CD50.R9 “Strengthening NRAs for medicines and biologicals”

• Challenges / Perspectives for the future
Background

• The Pan American Network on Drug Regulatory Harmonization (PANDRH) is formed by all Member States of the PAHO Region.

• This group is an initiative of all the National Regulatory Authorities in the Region and PAHO. It supports processes of drug regulatory harmonization in the Americas within the framework of current realities and national health and sub-regional policies while recognizing pre-existing asymmetries.

• PANDRHs networking components are:
  – The Pan American Conference
  – The Steering Committee
  – Technical working groups in priorities areas
  – Secretariat (PAHO)

• All information is published and available via the following links:
  – WWW.PAHO.ORG/PANDRH (in English)
  – WWW.PAHO.ORG/RedPARF (in Spanish)
PANDRHs Mission

“To promote the harmonization of pharmaceutical regulation covering aspects of quality, safety, efficacy and rational use of pharmaceutical products, the strengthening of National Regulatory Authority (NRA) capacity within the Region of the Americas based on the right of the population to access quality medicines, recognizing advances in science and technology and within the context of national and sub-regional realities”.

[PANDRH Steering Committee July 2009]
# 2011 PANDRHs Steering Committee

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PANDRHs Technical working groups

- PANDRH Technical working groups:
  - Bioequivalence
  - Good laboratory practices
  - Good manufacturing practices
  - Good clinical practices
  - Drug registration
  - Drug classification
  - Drug promotion
  - Pharmacovigilance
  - Combat to drug counterfeiting
  - Pharmacopoeia
  - Medical plants
  - Vaccines
  - Biotechnological products (its creation was approved by the SC on Jan 2010)
PANDRHs Objectives

- Strengthen regulatory authorities in countries of the Region promoting inter-country cooperation;
- Develop and approve harmonized proposals (technical documents, guidelines, etc.) in medicine’s regulation;
- Identify support mechanisms for the implementation, monitoring and evaluation of proposals adopted and approved by NRAs through PANDRH;
- Promote qualification of the NRAs in the Region in accordance with criteria established by PAHO/WHO and in order to establish reference Regulatory Authorities and contribute actively to the achievement of other objectives.
Update of current activities in the Americas Region regarding harmonization
Technical documents adopted by PANDRH as of 2010
As of 2010, PANDRH has adopted nine technical documents:

During the VI Pan American Conference on Drug Regulatory Harmonization held in Brasilia in July in 2011, the following documents were adopted:

- **Recommendation for the evaluation of biotherapeutical products (SBPs)**
- **Guidelines to be consider by the Health Authorities in light of suspected counterfeiting of medicines and medical products**
- **Guidelines for registering medicines in the Americas**
- **Researcher’s guidelines on manual for good clinical practice**
- **Guidelines for clinical pediatric trials**
- **Considerations on the use of placebos**
- **Ethical criteria for promoting, advertizing and publicizing drugs**
PANDRH and NRAs Strengthening

- By 2011, three official drug control laboratories were pre-qualified by WHO as United Nations Reference Laboratories:
  - CONCAMYT (Official Laboratory for Drug Quality Control and Toxicology) BOLIVIA
  - CNCC (Official Laboratory at the National Center for Quality Control) PERU
  - CCCM (Official Laboratory at the Commission for Drug Quality Control) URUGUAY
Resolution CD50.R9, 2010:
“Strengthening National Regulatory Authorities for Medicines and Biologicals”

“To urge the Member States to

a) strengthen and evaluate their regulatory capabilities with respect to the functions characteristic of a regulatory and oversight agency for medicines and biologicals, through an examination of the performance of their essential functions;

b) use the results of the qualification activity and the designation of the regulatory authorities of regional reference to strengthen their performance in terms of the steering role of the health authority;

c) support national regulatory authorities so they can benefit from the processes and information from national regulatory authorities of reference;

d) promote the dissemination of information on the results and processes for the regulation and oversight of medicines, biologicals, and other health technologies;

e) promote interaction and technical cooperation among countries;

f) actively participate in the Pan American Network for Drug Regulatory Harmonization (PANDRH).”
Challenges/ Perspectives for the future

- Prioritize Strengthening of National Regulatory Authorities:
  - Promote Good Regulatory Practices;
  - Promote partnerships and exchange between NRAs leading to optimization of resources;
  - Integrate with the work of PANDHR, and develop a strategic development plan for the Network, linking with other harmonization initiatives;
  - Promote the use of modern technological platforms for regulatory exchange, knowledge transfer and capacity building.
Promoting exchange of information between Member States on regulatory processes and functions: Regional Platform

**In that integrates tools, services and functions:**

- CoP
- Expert Locator
- Network Analysis
- Innovation Forum
- MedList
- Post Marketing Surveillance
- Registration Manufact Comercializat.
- Observatory
- Learning opportunities
- Editorial Sec
- Admin
- Network Analysis
- MedList
- Post Marketing Surveillance
- Registration Manufact Comercializat.
- Observatory
- Learning opportunities

**Initial Countries:** Argentina, Colombia,

USA, Panama, Dominican Republic
Regional Platform: Learning opportunities

- Integrated with PAHO’s Virtual Campus of Public Health
- Strengthening NRA core functions: Based on needs assessment resulting from NRA assessment
- Creation of Access and Innovation node that will house all available learning opportunities related to HT management in the public health sector
- Take advantage of existing courses and development of new ones

PAHO / FDA (USA): Cooperative Agreement (2010 – 2014) on the development of a virtual platform or regional hub to promote exchange of information between Member States on regulatory processes and functions.
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