CURRENT STATUS OF PAN AMERICAN NETWORK FOR DRUG REGULATORY HARMONIZATION (PANDRH):

OVERVIEW AND WORKING GROUP UPDATES

James Fitzgerald
Advisor Essential Medicines and Biologicals
PAHO Washington DC
PANDRH: Pan American Network for Drug Regulatory Harmonization

1. Establishes a Pan American Forum of Drug Regulatory Agencies (DRA) to discuss and search for solution of common problems, with DRAs leading and participating in the process.
2. Strengthens the establishment of priorities in drug regulatory harmonization processes and encourage convergence of drug regulatory systems in Region.
3. Improves access to quality, safety & efficacy drugs to improve quality of pharmaceutical markets.
4. Promotes technical cooperation where more developed DRA share knowledge and experiences with less advanced DRA.

Working Groups

- Good Manufacturing Practices
- Bioequivalence and Bioavailability
- Good Clinical Practices
- Drug Classification
- Counterfeit Drugs
- Good Laboratory Practices
- Pharmacopoeia
- Medicinal Plants
- Drug Registration
- Pharmacovigilance
- Vaccines
- Promotion and Marketing
PANDRH OPERATING SYSTEM

Pan American Conference

Steering Committee

Secretariat

Regulators
Andean Area
CARICOM
MERCOSUR
SICA
NAFTA
INDUSTRY

Consumers
Academia
Professional
Associations

WG
WG
WG
WG
WG
WG
Objectives of the Working Group

- Conduct comparative studies identifying differences in legislation and practices among countries;
- Exchange of national and sub-regional experiences;
- Formulation of proposals that facilitate regional harmonization of regulations;
- Identify strategies for the implementation of proposals adopted by the Conference;
- Implement country and sub-regional follow-up;
- Define plans for cooperation among countries;
- Support NRA in the process of implementation and dissemination of scientific knowledge;
UPDATE ON SOME OF THE WORKING GROUPS
Pharmacovigilance

Mission statement

• To develop and strengthen pharmacovigilance through activities and proposals of harmonized regulatory actions that promote the safe and rational use of drugs as a necessary component of Public Health policies in the Region of the Americas

Members: COL, BRA, CUB, CAN, URU, FIFARMA, ALIFAR
Objectives

- To promote the development and dissemination of knowledge, criteria and methodologies used in Pharmacovigilance to be used in training and education activities directed to all stakeholders related to medicines;

- To develop, analyze and propose the use of tools to support harmonization of Pharmacovigilance in the Region;

- To design and promote the work in network to exchange knowledge, communicate and support decision making related to pharmacovigilance;

- To foster the integration of pharmacovigilance as a necessary component of public health and medicines policies and programs;

- To promote research and dissemination of pharmacovigilance and its impact in public health with emphasis in patient safety.
Update

- The group has elaborated a series of documents:
  - Situational analysis of pharmacovigilance in the Americas;
  - Glossary of terms on pharmacovigilance;
  - Program for a workshop for NRA;
  - Document on Good Practices on Pharmacovigilance for centers;
DRUG PROMOTION

Mission statement

• To promote and harmonize criteria for drug promotion as a contribution to the rational use, within the scope of health policies in the Americas.

Members: ECU,BAR,COR,MEX,BRA,FIFARMA,ALIFAR
Objectives

• To provide mechanisms and criteria to identify irregularities and demonstrate the most frequently used market strategies for drug promotion;

• To provide information and analysis on regulation, implementation and monitoring related to drug promotion.

• To promote educational activities and programs related to drug promotion aimed at health professionals, potential and effective consumers.

• To evaluate the operation and impact of the activities of the WG.
Update

• For several NRAs, promotional activities perceived as adversely impacting national strategies for promoting the rational use of medicines.

• The workplan proposes a comparative study of legislation in countries on publicity of pharmaceuticals for some special products;
Vaccines

Mission statement

• Promote the harmonization of the requirements of vaccines in order to guarantee their quality, safety and efficacy, creating efficient mechanisms to contribute to vaccine availability to all countries in the region.

Members: CUB, VEN, ARG, CAN, BRA
Objectives:

- To harmonize requirements for authorization of vaccine clinical trials, and follow up activities that should take place to monitor this harmonization process.
- To harmonize technical requirements for the registration (marketing authorization) of vaccines; and monitor its implementation.
- To promote the exchange of information and the convergence and recognition of the vaccine regulation systems among the NRAs of the region.
- To set up tools and organize training activities for technical staff of NR agencies in the region.
- To harmonize GMP requirements, specifically for vaccines, and follow up activities should take place in order monitor this harmonization process.
- To promote the establishment of systems for the vigilance of Adverse Events Following Immunization (AEFI) in the region.
- To identify other important issues on vaccines regulation that may deserve special attention, and establish an appropriate working plan to address them.
Update

- Survey completed on licensing requirements for vaccines in Member States;
- Harmonized Guidelines (LA / Canada) developed for registration of vaccines to be presented to the PANDHR Conference, November 2008
Good Laboratory Practices

Mission statement

• Strengthen performance of OMCL in the countries of the Region of the Americas through the implementation of Good Laboratory Practice (GLP) to guarantee the quality of analytical results and facilitate their mutual recognition of them.

Members: CHI, BRA, PAN, JAM, USP
Objectives:

- Support the implementation of GLP in OMCL.
  - Preparation and dissemination of educational material for the implementation of GLP guidelines;
  - Elaboration of a program for training and continuing education;
  - Technical support to the countries that accept the commitment to implement GLP.

- Promote the establishment of an OMCL network.
  - Formalization of the EQCP.
  - Harmonization of reporting format for results.
  - Preparation of a proposal for the structure of the NETWORK
Up date

• Improving standardization of drug quality testing through the External Quality Control Program;
• Norms & procedures for EQCP;
• Training:
  – National courses in GLP;
  – Regional seminars on HPLC & Dissolution;
  – Evaluation tool for Quality Control Laboratories
Drug Counterfeiting

Mission Statement

• Promote, facilitate, and motivate implementation of proactive strategies for preventing and fighting drug counterfeiting and thus contribute to the improvement of health care in the Americas.

Members: BRA, STL, ARG, CAN, COL, FIFARMA, ALIFAR
Update

The group is working on:

- Developing the network;
- Adopting standards of Good Practices through the complete chain of commercialization;
- Identify mechanisms of medicines traceability;
- Develop educational seminars;
- Coordinate actions with IMPACT.
PANDHR Conference November 2008, Buenos Aires, Argentina

• Working Groups
  – Review / adoption of regional harmonized norms and guidelines produced by the Working Groups
  – Update on activities of Working Groups

• Presentation of NRA assessment tool
  – adapted from WHO Guidelines by 7 NRAs in LA
  – focuses on core functions defined by the NRAs
  – recognizing NRAs supporting regional prequalification through the Strategic Fund

• Presentation of revised statutes:
  – focus on prioritization and decision making process
  – scope of activity for Working Groups, role in capacity building
  – strengthening participation and articulation with sub-regional blocs
PANDHR Sub-regional Blocs

NAFTA
MERCOSUR
SICA
ANDEAN COMMUNITY
CARICOM
THANK YOU