Quality and Regulation of Medicines and Health Technologies:

Update from PAHO/AMRO Region:

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V PANDRH Conference, Argentina, 17-19 November 2008

- Presentation and Introduction by Director PAHO/WHO, Americas and Director of ANMAT, Argentina;
- >250 participants, NRAs, Industry, Academia, accredited PAHO/WHO NGOs;
- Keynote Presentations, Panel Presentations, WG Discussions, Conference meeting and adoption of harmonized technical documents.
Principle Themes of V Conference

- Pharmaceutical Regulation and Public Health (PAHO/WHO and ANMAT Argentina)
- Update on Drug Regulatory Harmonization Initiatives
  - ICDRA, ICH, PANDRH and ASEAN Initiatives
- System for Inter-ARN Recognition (PAHO/WHO & CECMED (Cuba))
  - Adoption of a transparent and uniform methodology for evaluating ARN core functions;
- Counterfeiting as a Public Health Problem (WHO)
  - Update on global and regional activities with discussion on definition.
- WHO Prequalification (WHO)
  - Presentation of scope, process and technical documentation
- Rational Use as a Component in Regulatory Decisions (CC/PAHO)
  - Regulation of information on use of medicines, monitoring of marketing of medicines
Technical Documents Adopted (8)

- BE: Framework for Implementation of Equivalence Requirements for Pharmaceutical Products*
- PV: Good Pharmacovigilance Practices*
- Vaccines: Harmonized Requirements for the Registration of Vaccines in the Region of the Americas
- Vaccines: Guidelines for Preparation of a request for registration.
- GCP: Guidelines for conducting clinical studies in pediatric populations*
- GMP: Decision tree for the Implementation of the Guidelines for Good Manufacturing Practices Inspection
- GMP: Good Manufacturing Practices for Pharmaceutical Ingredients (ICH-Q7)
- GMP: Code of Ethics for Inspectors of Good Manufacturing Practices

* with changes suggested by the Conference
Update from selected PANDRH WGs (1)

- **Biotechnological Products:**
  - Creation of a PANDRH technical working group on biotechnological products
  - Regional meeting on regulation of biotechnological products and First meeting of the PANDRH biotechnological products working group [June 2010, Dominican Republic]
  - Members: ARG, BRA, PER, GUT, T&T, BAR, CAN, CUB, VEN, FIFARMA, ALIFAR

- **Vaccines**
  - Development of the Plan of Work to monitor implementation of Harmonized Guidelines for Registration.

- **Pharmacovigilance:**
  - Good Pharmacovigilance Practices for the Americas. Validated by Colombia. Adopted by subregional groups: the Andean Region and individual countries (Colombia, Argentina).
  - Virtual Training of 20 representatives from seven countries. Next scheduled course 2011.

- **Counterfeit / Falsification of Medicines:**
  - Workshop for Prevention and Combat of Counterfeit Medicines: “Establishing an inter-sectoral partnership and a plan of action”.
  - Panama, Bolivia, Jamaica / OECS: Plan of work, revision of legislation, task force.
  - Under development: Inspection guidelines and Network of Focal Points
Update from selected PANDRH WGs (2)

- Good Laboratory Practices:
  - GLP workshops in Argentina and Panama
  - Workshop with ANVISA and LACEN, Brazil.
  - Support to OMCLs in the WHO External Quality Control Program

- Three Regional OMCLs achieve WHO Prequalification as Reference Quality Control Laboratories for the United Nations (Sep 2010).
  - CONCAMYT (Official Laboratory for Toxicology and the Quality Control of Medicines), Bolivia.
  - CNCC (Official Laboratory, National Centre for Quality Control), Peru.
  - CCCM (Official Laboratory, The Commission for the Quality Control of Medicines) Uruguay
  - All labs are certified ISO 9001 and/or ISO 17025 and have been active participants in the PAHO/WHO external quality programs.
Strengthening Regulatory Authorities in Medicines and Biologics (CD50.R9), 2010 (1).

- Latin American Regulators and PAHO/WHO identify need to establish a transparent and uniform methodology for evaluating NRA performance and core functions (2007);
- Initial participation of Latin American Regulators (7) with consensus on tool and indicators, Mexico, July 2008.
- Evaluation guide and SOPs for evaluation developed (2009).
- Experts selected from regional and other reference NRAs (Spain, Portugal).
- Assessments completed in Argentina, Brazil, Colombia, Chile, Cuba, and pre-assessments in the Dominican Republic, El Salvador, Guatemala, Paraguay (2010).
- Process: Virtual meetings between evaluation team and ARN, definition of agenda, signing of conflict of interest and confidentiality agreement, presentation of the assessment tool, pre-filling of the tool by the ARN, assessment by the evaluation team, discussion of results and development of work plan, final report.
Strengthening Regulatory Authorities in Medicines and Biologics (CD50.R9), 2010 (2).

- Anmat (Argentina), Brazil (Anvisa), Colombia (Invima) and Cuba (CECMED) classified as ARNs, Level IV, ‘….competent and efficient in the implementation of standards necessary to ensure the quality, safety and efficacy of medicines’.

- Member States at the PAHO Executive Committee request discussion of initiative within the Directing Council, PAHO, June 2010.

- PAHO Directing Council takes up the discussion, Resolution adopted by Member States, with 15 country interventions providing strong endorsement for the initiative.
To request Member States:

a) strengthen and evaluate their regulatory capacity with respect to the functions characteristic of a regulatory 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;…

To Request the Director:

a) support initiatives for the strengthening and qualification of national regulatory authorities to guarantee the quality, safety, and efficacy of medicines, biologicals, and other health technologies;……

c) maintain and strengthen the collaboration of the Pan American Health Organization with the Member States in the area of medicines and biologicals regulation;

d) promote technical cooperation among country regulatory authorities as well as recognition of the existing capacity in the Region;……
Increasing Regional Integration and Cooperation

- **UNASUR**: integration of South American countries, with a 5 year work plan in Access to Medicines adopted and in implementation.

- **ALBA**: Bolivia, Cuba, Dominica, Ecuador, Nicaragua, Venezuela; Project ALBAMED focusing on common registration process for medicines used in public health programs.

- **CARICOM / WB / PAHO**: Study on regulatory capacity and options in harmonization; recommendations incorporated into Regional Pharmaceutical Policy to be presented at COHSOD, April 2011.

- **PAHO / ANVISA**: Cooperative Agreement (2010 – 2015) to strengthen regulatory capacity, in particular in areas of HTA, regulation of the promotion of medicines, norms and standards in medicines.

- **PAHO / FDA**: 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.

- **BID / AECID**: Central America, assessments to determine opportunities for harmonization of pharmaceutical regulations.
Perspectives for 2010 - 2012

– Implementation of the Resolution CD50.R9 to Strengthen National ARNs:
  • Integration of medicines and biologics / vaccines evaluations with support from ARNs of regional reference;
  • Using installed capacity to promote inter-NRA collaboration;

– Promoting exchange and links between NRAs, networking to ensure capacity building:
  • Through PANDRH and its WGs, and implementation of regional cooperation projects with partners;

– Organization of VI PANDRH Conference, Brazil, July 2011.
  • A focus on health systems and regulatory capacity;
  • Consolidation of WGs and presentation of working documents;
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