



# BULLETIN OF MEDICINES AND HEALTH FOR THE AMERICAS

Pharmaceutical Forum of the Americas

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### V Conference of the Pan American Network for Drug Regulatory Harmonization (PANDRH)

The V Conference was held in Buenos Aires, Argentina, during November 17<sup>th</sup> to19<sup>th</sup>, 2008. PANDRH is integrated by the Regulatory Agencies of 35 countries of the Region and representatives from FIFARMA and ALIFAR. Also with the participation of pharmaceutical industry, patient's associations, universities and other interested groups. Nowadays, PAHO/WHO is in charge of the Secretary of PANDRH, acting as a facilitator. Its mission is to promote harmonization of all aspects of medicine regulations about quality, safety and efficacy, as a contribution to quality of life and health care of the population of the Americas.

During the conference, the working groups presented and debated background and current work. The technical documents were submitted to debate and revision.

As a result of the Conference, several documents were approved and they will be implemented in the participating countries:

Working Group on Bioequivalence: Framework for implementation of Equivalence Requirements for Pharmaceutical.

Working Group on Pharmacovigilance: <u>Good</u> <u>Pharmacovigilance</u> Practices for the Americas. <u>Document of Public opinion.</u>

**Working Group on Vaccines**: <u>Proposed</u> <u>Harmonized Requirements for the Licensing of</u> <u>Vaccines in the Americas and Guidelines for</u> <u>preparation of applications.</u>

Working Group on Good Clinical Practice: Guide for Conducting Clinical Studies in Pediatric Populations. **Working Group on Good Manufacturing Practice**: Decision tree for the implementation of the Guideline for good manufacturing practices inspection, Guide of Good Manufacturing Practice for active pharmaceutical ingredients (Guide ICH-Q7) and Code of Ethics for Good Manufacturing Practice inspectors.

**Working Groups on Counterfeit Medicines**: The definition of counterfeit medical product was discussed.

Whereas, is available the <u>"Preliminary Report of the activities on its findings and recommendations</u>".

To access to presentations and the rest of documents presented during the <u>Conference visit</u> the V Conference of the Pan American Network for Drug Regulatory Harmonization Web Site.

### 8th International Society of Pharmacovigilance Annual Meeting



For first time, the Annual Meeting of the International Society of Pharmacovigilance was held in Latin America. The event took place in October 5-7 2008, in Buenos Aires, Argentina. The slogan chosen was "Strategies for the development of Pharmacovigilance". Meeting counted with around 350 The participants from 50 countries. During the 3 days of the meeting, it was discussed about harmonization of pharmacovigilance, counterfeit and sub-standard medicines, pharmacovigilance in special populations, among others topics. There were also sessions about risk management, biological products and communication.

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There was a session of Counterfeit and Sub-Standard medicines, with participation of PANDRH, PAHO/WHO and the Pharmacovigilance Society of Argentina. The speakers developed background and current situation of this matter in our Region. The weak points of the Region were highlighted, such as regulation, lack of cooperation among sectors, lack control in commerce, weak control and enforcement measures and the high price of medicines. It is estimated that counterfeit medicines represent in developing countries over the 25% of all medicines consumed by the

### VI Pan-American Conference on Pharmaceutical Education

The sixth edition of the Conference held place during November 19 to 21, 2008, in Montevideo, Uruguay. The event counted with organization of the School of Chemistry of Uruguay, the support of PAHO/WHO, and was held in the same frame of the FEFAS Congress.

Several workshops were organized with the purpose of debating and reaching a consensus on the future of Pharmaceutical Education an on accreditation proposal for the Pharmacy Career in Latin America.

#### Accreditation Workshop and Basic Plan:

The working group comprised defined analyzed Accreditation Proposal by participants. They changed and incorporated different matters. They participants also analyzed contributions sent by interested partners.

A Working Group integrated by representatives of 12 countries was formed as a result of this workshop. This group will continue working on regarding consensus and optimization of the Accreditation Proposal. A Coordinating Committee was also formed with the participation of member of PAHO/WHO and the Working Group.

#### Auto assessment and Basic Plan Workshop:

The Working Group conformed during this workshop defined basic needs work, such as development of a glossary, background analysis, work methodology and collection of indicators, courses modality and other elements.

## Education on Good Pharmacy Practice Workshop:

The Working Group recommended including Good Pharmacy Practice (GPP) in subjects that give training of in patient care to Pharmacy students. They also recommended training practices in institutions GPP compliance with accredited tutors

## Pharmaceutical Care and Rational Use of Medicines Workshop:

Members of the workshop conducted a situation analysis of the profession in regard with Pharmaceutical Care and Rational Use of Medicines. Based on this background, they determined the critic factors in which to focus efforts.

#### Pharmacy Students of the Americas Workshop:

A workshop was developed with the participation of pharmacy students from countries of all Americas. They carried out a debate on the current situation of the profession in each country. Subjects as working conditions, joining of professional associations and accreditation were discussed.

A meeting was held between representatives of the 21 participating countries to debate the structure and functioning of the next Conferences of Education.

One of the most important definitions of this meeting was determination of making conference every two years, contrasting the former period of three years. The requirements of the future venues were defined. The organizer should have political and institutional support, and logistics, organization capacity, among other characteristics. The attendants determined that it would be desirable to hold the Conference in the frame of another event relevant to pharmacists, to facilitate organization and attendance to meeting.

The selection of the next venue for the Conference was submitted to vote. Brazil was elected to hold the next event, in the year 2010.

The profile of country delegates was defined. Their period of activity was extended to four years, in order to cover at least two conferences.

The committees of Basic Curricula and Accreditation were conformed from the Working Groups of the Workshops developed during the Conference.

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