

V CONFERENCE OF THE PAN AMERICAN NETWORK FOR DRUG REGULATORY HARMONIZATION (PANDRH)

**Buenos Aires, Argentina
November 17th – 19th, 2008**

Agenda

November 16th

5:00 - 7:00 PM Registration *

November 17th

8:00 - 9:00 am Registration*

9:00 - 9:30 am **Opening:** Welcoming speech of the National and PAHO/WHO authorities.

9:30 - 10:00 am **Regulation and Public Health. Video of Dr. Mirta Roses, Director of PAHO/WHO.**

10:00 -10:30 am **PANDRH: Working methodology.**
PAHO/WHO Secretariat

10:30 - 10:45 am Coffee break

10:45 - 12:30 am **Panel: Harmonization Initiatives of Pharmaceutical regulation.**
Coordination: NRA of Colombia.
ICDRA: Lembit Rago (WHO); ICH: Justin Molzon (FDA); PANDRH: José Luis Di Fabio (PAHO/WHO); ASEAN: Selvaraja Seerangam (Ministry of Health, Malaysia)

12:30 - 2:00 pm Lunch

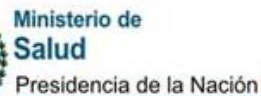
2:00 - 2:45 pm **The self assessment and recognition of Regulatory Authorities.**
Rafael Pérez Cristiá, CECMED-Cuba and José Peña, PAHO/WHO.

2:45 - 4:15 pm **Presentation of the progress and achievements of the working groups (WG).**
Coordination: NRA of Costa Rica.
Bioequivalence (BE): Justin Molzon (FDA, USA), Ricardo Bolaños (ANMAT, Argentina), Silvia Giarcovich (ALIFAR, Argentina).
Pharmacovigilance (PhV): Rubiela Méndez (INVIMA, Colombia), Claudia Vacca (UNAL, Colombia).
Vaccines (V): Olga Lidia Jacobo (CECMED, CUBA). .

4:15 - 5:30 pm **Coffee Break and discussion sessions of the working groups.**

5:30 - 6:30 pm **PANDRH session**

* (4th floor of the NH City hotel, Bolívar 120)



November 18th

8:30 - 9:15 am

Essential functions in medicines regulation and challenges for the Regulatory authorities.

José Luis Di Fabio, PAHO/WHO.

9:15 - 09:45 am

Medicines counterfeiting: a Public Health problem.

Valerio Reggi, WHO.

09:45 - 10:15 am

The prequalification system of WHO.

Lembit Rago, WHO.

10:15 - 10:45 am

Coffee break

10:45 - 12:30 pm

Presentation of the progress and achievements of the working groups (WG).

Coordination: NRA of Argentina.

Medicines Registration (DR): María Teresa Ibarz (INHRR, Venezuela).

Good Laboratory Practices (GLP): María Gloria Olate (ISPCH, Chile).

Counterfeit medicines (CDC): Tiago L. Rauber (ANVISA, Brazil).

12:30 - 2:00 pm

Lunch

2:00 - 3:30 pm

Presentation of the progress and achievements of the working groups (WG).

Coordination: NRA of Jamaica.

Good Clinical Practices (GCP): Analía Pérez (ANMAT, Argentina)

Medicines promotion (DP): María José Delgado (ANVISA, Brazil)

Good Manufacture Practices (GMP): Justin Molzon (FDA, USA), Rodolfo Mochetto (ANMAT, Argentina), Rosalba Alzate de Saldarriaga (consultant, PAHO/WHO).

3:30 - 4:30 pm

Coffee Break and discussion sessions of the working groups.

4:30 - 6:30 pm

PANDRH session.

November 19th

8:30 - 9:00 am

The rational use of medicines as a component of regulatory decisions.

Perla de Buschiazzi, CUFAR, Collaborating Center of PAHO/WHO, Argentina.

9:00 - 10:30 am

Round table: Biotechnological biologic products.

Coordination: María Ángeles Cortes Castillo, PAHO/WHO.

PAHO/WHO: Mariluz Pombo, ALIFAR: Néstor Anníbal, FIFARMA: Lucas Marletta, Canadian Regulatory Authority (Health Canada): Elwin Griffiths.

10:30 - 11:00 am

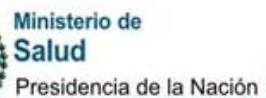
Coffee break

11:00 - 12:30 am

Panel: Progress in the incorporation of PANDRH's recommendations in the Regional integration processes.

Coordination: NRA of Brazil.

MERCOSUR: , ANDEAN COMMUNITY: , COSTUMS ORGANIZATION: Julio Valdés, CARICOM:



12:30 - 2:00 pm

Lunch

2:00 - 4:00 pm

Conclusions and Recommendations.

4:00 - 4:45 pm

Closing session.

ANMAT, PAHO/WHO, ALIFAR, FIFARMA, Directive committee of the PANDRH.

