
The Conference is the highest instance of the PANDRH Network, supported by Resolution CD42.R11 on Drug Regulatory Harmonization, approved by the 42nd Directive Council of PAHO in 2000. Participants to the Conference are: national regulatory authorities from PAHO Member States; the drugs and generics research industry, academic circles; consumer’s organizations; and other groups of interest.

This Conference is an opportunity to find convergence of the Drug Regulation Systems in the Americas and to establish constructive dialogue among the regulatory institutions and other groups of interest.

Opening Remarks


Documents

- Agenda. V Conference of the Pan American Network for Drug Regulatory Harmonization (PANDRH) (223.16 kB)

- (PANDRH): Information and propositions of nine (9) working groups presented for consideration (117.59 kB)


Technical Working Groups Documents

Working Group on Bioequivalence

- Framework for implementation of Equivalence Requirements for Pharmaceutical. Proposal to be submitted to the V Conference for Drug Regulatory Harmonization. (503.57 kB)

- Document approved in the V Conference for Drug Regulatory Harmonization:
  - Framework for implementation of equivalence requirements for pharmaceutical products. Document approved in the V Conference for Drug Regulatory Harmonization (326.45 kB)

Working Group for Prevention and Combat of Counterfeiting of Medicines

Documents (161 kB)

Good Pharmacovigilance Practices

Documents (402.31 kB)

Good Clinical Practices

Draft under discusion. Guide for conducting clinical studies in pediatric populations. (77.48 kB)

Working Group on Good Manufacturing Practices

Documents (179.75 kB)

Informe de actividades educativas presentado a la V Conferencia de la Red Panamericana para la Armonización de la Reglamentación Farmacéutica. (only in Spanish)

Decision tree for the implementation of the Guideline for good manufacturing practices inspection

Working Group on Medicines Promotion

V Conference PANDRH. Argentina, November 2008 (only in Spanish)

Working Group on Registration of Medicines


Vaccines

Working Group of Vaccines (127.42 kB)


Working Group on Good Laboratory Practices

Good Practices Self Evaluation Guide for National Pharmaceutical Control Laboratories. (448.94 kB)
Web Page with documents: Working plan, directory, and meeting reports.

**Presentations V Conference PANDRH**

**PANDRH: Working methodology. PAHO/WHO Secretariat** - Presentation (373 kB)

**Panel: Harmonization Initiatives of Pharmaceutical regulation. Coordination: NRA of Colombia.**

- ICDRA: Lembit Rago (WHO) - Presentation (541.5 kB) (Only Spanish)
- ICH: Justin Molzon (FDA) - Presentation (1.12 MB)
- PANDRH: José Luis Di Fabio (PAHO/WHO) - Presentation (586.5 kB) (Only Spanish)
- ASEAN: Selvaraja Seerangam (Ministry of Health, Malaysia) - Presentation (836.5 kB)
- The self assessment and recognition of Regulatory Authorities.
- Rafael Pérez Cristiá, CECMED-Cuba - Presentation (4.8 MB) (Only Spanish)
- José Peña, PAHO/WHO - Presentation (10.67 MB) (Only Spanish)

**Presentation of the progress and achievements of the working groups (WG). Coordination: NRA of Costa Rica.**

Bioequivalence (BE)

- Justin Molzon (FDA, USA) - Presentation (1.17 MB) (Only Spanish)
- Ricardo Bolaños (ANMAT, Argentina) - Presentation (83 kB) (Only Spanish)
- Silvia Giarcovich (ALIFAR, Argentina) - Presentation (262 kB) (Only Spanish)
- Pharmacovigilance (PhV):
- Rubiela Méndez (INVIMA, Colombia), Claudia Vacca (UNAL, Colombia).

Vaccines (V):

- Olga Lidia Jacobo (CECMED, CUBA) - Presentation (241 kB) (Only Spanish)

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

José Luis Di Fabio, PAHO/WHO. - Presentation (3.42 MB) (Only Spanish)


- Valerio Reggi, WHO. Valerio Reggi, OMS - Presentation (7.54 MB) (Only Spanish)

The prequalification system of WHO. Lembit Rago, WHO - Presentation (5.36 MB)

**Presentation of the progress and achievements of the working groups (WG). Coordination: NRA of Argentina.**

Medicines Registration (DR):

- María Teresa Ibarz (INHRR, Venezuela). Presentation (155 kB) (Only Spanish)
Good Laboratory Practices (GLP):

María Gloria Olate (ISPCH, Chile) - Presentation (10.07 MB) (Only Spanish)

Counterfeit medicines (CDC):

Tiago L. Rauber (ANVISA, Brazil) - Presentation (322.5 kB) (Only Spanish)

**Presentation of the progress and achievements of the working groups (WG). Coordination: NRA of Jamaica.**

Good Clinical Practices (GCP):

Analía Pérez (ANMAT, Argentina) - Presentation (798 kB) (Only Spanish)

Medicines promotion (DP):

Maria José Delgado (ANVISA, Brazil) - Presentation (201 kB) (Only Spanish)

Good Manufacture Practices (GMP):

Justin Molzon (FDA, USA) - Presentation (19.58 MB)

Rodolfo Mochetto (ANMAT, Argentina) - Presentation (157 kB) (Only Spanish)

Rosalba Alzate de Saldarriaga (consultant, PAHO/WHO).


Analía Pérez (ANMAT, Argentina) - Presentation (798 kB) (Only Spanish)

**Round table: Biotechnological biologic products. Coordination: María Ángeles Cortes Castillo, PAHO/WHO.**

- PAHO/WHO: Marí Luz Pombo - Presentation (2.98 MB) (Only Spanish)
- ALIFAR: Néstor Annibali - Presentation (1.32 MB) (Only Spanish)
- FIFARMA: Lucas Marletta - Presentation (1.03 MB) (Only Spanish)
- Canadian Regulatory Authority (Health Canada): Elwin Griffiths - Presentation. (766.5 kB)

Panel: Progress in the incorporation of PANDRH’s recommendations in the Regional integration processes. Coordination: NRA of Brazil.

- MERCOSUR: Presentation (51.5 kB) (Only Spanish)
- Andean Community: Presentation (312 kB) (Only Spanish)
- Costums Organization: Julio Valdés, Presentation. (770.5 kB)
- CARICOM: - Presentation (820 kB)

Conclusions and Recommendations.

Closing remarks

- Presentación. ALIFAR. Rubén Abete (72.5 kB) (Only Spanish)