V Conference of the Pan American Network for Drug Regulatory Harmonization (PANDRH) Buenos Aires, Argentina – 17 to 19 November 2008.

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

Regulation and Public Health. Video. Dr. Mirta Roses Periago, Director - Pan American Health Organization, Pan American Sanitary Bureau. Regional Office of the World Health Organization (Only in Spanish)

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)

World Health Organization. WHO Technical Report Series, No. 937, 2006. Annex 5. Good distribution practices for pharmaceutical products. (5.33 MB)

PANDRH Norms and Procedures. Buenos Aires, Argentina, 2008. (Discussed in Plenary Session, November, 2008). (157.04 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)

Bioequivalence and Bioavailability Working Group. Proposals to the V Conference. Buenos Aires, Argentina, 17- 19 November, 2008. (2.51 MB) (*PowerPoint*)

Working Group for Prevention and Combat of Counterfeiting of Medicines

Working Group for Prevention and Combat of Counterfeiting of Medicines Documents (161 kB)

Good Pharmacovigilance Practices

Good Pharmacovigilance Practices for the Americas (402.31 kB)

Good Clinical Practices

Good Clinical Practices Working group. Draft under discusion. Guide for conducting clinical studies in pediatric populations. (77.48 kB)

Working Group on Good Manufacturing Practices

Working Group on Good Manufacturing Pratices 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

Working Group on Medicines Promotion. V Conference PANDRH. Argentina, November 2008 (58.15 kB) (only in Spanish)

Working Group on Registration of Medicines

Proposal of Harmonized Requirements for Drug Registration in The Americas. November, 2008. (159.61 kB)

Vaccines

Working Group of Vaccines (127.42 kB)

Proposed Harmonized Requirements for the Licensing of Vaccines in the Americas. Proposal version 11.04.2008.

Guidelines vesion 11/04/2008. Proposed Harmonized Requirements for the Licensing of Vaccines in the Americas. Guidelines for preparation of applications.

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)

Medicines counterfeiting: a Public Health problem.

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):

María 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).

Presentación de los Avances de los Grupos de Trabajo. Coordinación: ARN Jamaica.

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

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

- PAHO/WHO: María Luz Pombo - Presentation (2.98 MB) (Only Spanish)
- ALIFAR: Néstor Anníbali - 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.

Report of the V Pan American Conference on Drug Regulatory Harmonization, Buenos Aires, Argentina. November 2008 (1.27 MB)

Closing remarks

- Presentación. ALIFAR. Rubén Abete (72.5 kB) (Only Spanish)
- Acción Internacional para la Salud. AIS Latino América & Caribe Declaración de Acción Internacional para la Salud en la V Conferencia Panamericana de Armonizacion de la Regulacion Farmacéutica (Buenos Aires. Noviembre 17-19 de 2008) (Only Spanish)