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

Date: 21-23 August 2024.

Venue: Ministry of Foreign Affairs of Mexico (SRE), Salón José María Morelos y Pavón, 1st floor, Plaza Juárez No. 20, Colonia Centro, Demarcación Territorial Cuauhtémoc, Mexico City, Mexico.

Day 1
21 August 2024

7:40 AM  Participant registration, SRE Building.

8:00 AM  Reception of Ministers of Foreign Affairs

8:30 AM  (30')  Opening Ceremony
Presentation of the Presiding Committee and welcome remarks

- Judit Rius Sanjuan, Director, Department of Innovation, Access to Medicines and Health Technologies (IMT) at PAHO/WHO, representing the PANDRH Secretariat
- Dr. José Moya, Representative of PAHO/WHO, Mexico
- Dr. Jarbas Barbosa da Silva Junior, Director of PAHO/WHO (video)
- Alfredo Rimoch Lewinberg, Representative of the National Pharmaceutical Industry
- Dr. Alejandro Svarch Pérez, Federal Commissioner for Protection against Sanitary Risks, COFEPRIS
- Dr. Jorge Carlos Alcocer Varela, Secretary of Health of Mexico
- Dr. Alicia Bárcena Ibarra, Secretary of Foreign Affairs of Mexico

9:00 AM  (15')  Break

9:15 AM  (105')  Ministerial Dialogue: Diplomacy for regional convergence, integration, and cooperation towards access and productive development of health technologies in the Americas.

Moderator:
Emb. Joel Hernández García, Undersecretary of Multilateral Affairs and Human Rights, SRE

Opening:
- Dr. Alejandro Svarch Pérez, Federal Commissioner, COFEPRIS
- Judit Rius Sanjuan, Director, IMT Department, PAHO/WHO
11:00 AM (30’)

25th Anniversary of PANDRH


Objectives of the XI Conference.

- Judit Rius Sanjuan, Director, IMT Department, PAHO/WHO
- Maria Luz Pombo, Unit Chief, Quality and Regulation, IMT, PAHO/WHO

11:30 AM (30’)

Official photo

12:00 AM (90’)

Lunch

1:30 PM (75’)

Plenary session 1

The role of the State as a promoter of regional innovation and production of health technologies through its regulation.

- Alejandro Svarch Pérez, COFEPRIS (Mexico)
- José Luis Di Fabio, CEPI
- Francisco Rossi, INVIMA (Colombia)
- Michelle Rodríguez, FDA (United States of America)
- Patricia Carmona, ISP (Chile)
- Santiago Dueñas Carrera, BioCubaFarma (Cuba)

Moderators:
Francisco Caccavo and María Luz Pombo, PAHO/WHO

2:45 PM (90’)

Plenary session 2

The role of the pharmaceutical industry in self-sufficiency in health matters and pharmaceutical market integration.

- Joaquín García, CANIFARMA
- Augusto Muench, CANIFARMA
- Héctor Orellana, AMID
- Rubén Abete, ALIFAR
- Astrea Ocampo, AMELAF
- Yaneth Giha, FIFARMA
- Patrick Devlyn Jr., CCE
- Julio Ordaz, AMIIF
- Miguel Gerardo Lombera, ANAFAM
- Jaime López de Silanes, CFM

Moderator:
Mario Cimoli, COFEPRIS/UAM-X

4:15 PM (30’)

Coffee break
Plenary session 3

Strengthening regulatory systems in the oversight of local production of medical products.

- Ana Carolina Moreira Marino Araujo, ANVISA (Brazil)
- Juan Carlos Valverde, Ministry of Health (Costa Rica)
- Karla Delgado, ANRS (Nicaragua)
- Maryam Hinds, BDS (Barbados)
- Olga Lidia Jacobo Casanueva, CECMED (Cuba)

Moderator:
Catherine Parker, PAHO/WHO

6:00 PM
Day 1 Wrap-up

Day 2
22 August 2024

7:40 AM
Participant registration, SRE Building.

8:00 AM
Prospects for the Americas in building health self-sufficiency.

- Dr. Alicia Bárcena Ibarra, Secretary of Foreign Affairs of Mexico

8:30 AM
Plenary session 4
Building and strengthening efficient regulatory systems for medicines and other health technologies.

- Regulatory capacity building, evaluation, and recognition at the regional and global levels: tools and impact
  - Antonio Barra Torres, ANVISA (Brazil)
  - Karla Delgado, ANRS (Nicaragua)
  - Noe Geovanni García Iraheta, DNM (El Salvador)

Moderator:
José Daniel Peña, PAHO/WHO

- Advances in the use of regulatory reliance practices for the regulation of health technologies.
  - Chrystal Samouge, Ministry of Health and Welfare (Belize)
  - Hiiti Sillo, WHO
  - Maria Antonieta Román Tiburcio, FIFARMA
  - Martin Harvey, EMA

Moderator:
José Luis Castro, PAHO/WHO

11:00 AM
Coffee break
Panel A
Regulatory preparedness for epidemics and pandemics
- Danny Cascante Álvarez, Ministry of Health (Costa Rica)
- Diego Salas, FIFARMA
- Heriberto García, ISP (Chile)
- Jean Hu-Primmer, Moderna
- María Teresa Ibarz, PAHO/WHO
- Pearl McMillan, Ministry of Health and Welfare (The Bahamas)

Moderators:
April Hernandez, CEPI; María Teresa Ibarz and José Luis Castro, PAHO/WHO

Panel B
Clinical trials
- Agustina Bisio, ANMAT (Argentina)
- Carla Sáenz, PAHO/WHO
- Francisca Rodríguez, FIFARMA
- Patricia Saidón, PAHO/WHO

Moderator:
Patricia Saidón, PAHO/WHO

Plenary session 5
Initiatives and tools for competency-based continuing professional development of human resources in the regulatory field.
- David Rosales Muyaes, COFEPRIS (Mexico)
- Gladys Skoumal y María Teresa Ibarz, PAHO/WHO
- Karen López Montoya, ARSA (Honduras)

Moderator:
Gabriel Listovsky, PAHO/WHO

Panel C
Integrated approaches to strengthening regulatory systems: funding, technical assistance, and partnerships
- José Luis Di Fabio, CEPI
- Hiiti Sillo, WHO
- Ana Carolina Moreira Marino Araujo, ANVISA (Brazil)
- Leonardo Semprún, EFPIA LATAM Regulatory Network, Rise for Health

Moderator:
Michael Schmitz, USP

Panel D
Post-marketing surveillance
- Diana González, FIFARMA
- Miriam Loera, COFEPRIS (México)
- Naiffer Romero, USP (United States of America)
- Romina Viñas, ANMAT (Argentina)
- Verónica Vergara, ISP (Chile)

Moderator:
Edgard Rojas, PAHO/WHO

Day 2 Wrap-up
Day 3
23 August 2024

8:00 AM
Participant registration, SRE Building.

8:30 AM
Plenary session 6
Challenges of regulation systems for medical devices
  • Doris Yolima Gómez, INVIMA (Colombia)
  • Hiiti Sillo, WHO
  • Karen de Aquino Noff, ANVISA (Brazil)
  • Mario César Muñiz, CECMED (Cuba)
  • Sandra Ligia González, IACRC
Moderator:
  Nilda Enríquez Rodríguez, PAHO/WHO

10:00 AM
Coffee break

10:30 AM
Plenary session 7
Digitization for more efficient regulatory processes.
  • Alexandro Molina, COFEPRIS (México)
  • Dorian Salinas and Marlon Alvarado, ARSA (Honduras)
  • Joaquim Berenguer Jornet, EMA
  • Joe MacDougall, FDA (United States of America)
  • Michael Schmitz, USP (United States of America)
Moderator:
  Murilo Freitas and Alejandra Carrillo Roa, PAHO/WHO

11:30 AM
Plenary session 8
Digital sales of medicines and medical devices.
  • Eduardo Franciosi, ALIFAR
  • Joe MacDougall, FDA (United States of America)
  • Manuel Haces Aviña, Meta Mexico
  • Maria Rosa Hermida Cruells, Mercado Libre
  • Sandra Montoya, INVIMA (Colombia)
Moderator:
  Edgard Rojas, PAHO/WHO

12:30 PM
Lunch
Plenary session 9
Artificial intelligence and its impact on the regulation of health technologies.

- Joaquim Berenguer Jornet, EMA
- Marcelo D’Agostino, PAHO/WHO
- Ryan Hoshi, FIFARMA
- Tala Fakhouri, FDA (United States of America)

Moderator:
Sebastián García Saiso, PAHO/WHO

Conclusions, adoption of recommendations

- Judit Rius Sanjuan, PAHO/WHO
- Alejandro Svarch Pérez, COFEPRIS

Commemorative Marking of the XI CPARF Stamp and Closing Ceremony

- Rocío Bárcena Molina, Directora General del Servicio Postal Mexicano
- Luis Gilberto Murillo Urrutia, Ministro de Relaciones Exteriores, Colombia
- Dra. Alicia Bárcena Ibarra, Canciller de México
- Dr. José Moya, Representante de la OPS/OMS, México

End of the Conference