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.

Preliminary Agenda (as of August 13, 2024)

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  (30')

Prospects for the Americas in building health self-sufficiency.
- Dr. Alicia Bárcena Ibarra, Secretary of Foreign Affairs of Mexico
- Dr. Jorge Carlos Alcocer Varela, Secretary of Health of Mexico

9:30 AM  (30')

Official photo and coffee break
10:00 AM (90') Ministerial Dialogue: Diplomacy for regional convergence, integration, and cooperation towards access and productive development of health technologies in the Americas.

Opening:
- Dr. Alejandro Svarch Pérez, Federal Commissioner, COFEPRIS
- Judit Rius Sanjuan, Director, IMT Department, PAHO/WHO

11:30 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

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)
- Danielle Craig, CEPI
- Francisco Rossi, INVIMA (Colombia)
- Michelle Rodriguez, FDA (United States of America)
- Patricia Carmona, ISP (Chile)
- Santiago Dueñas Carrera, BioCubaFarma (Cuba)

Moderators:
- Francisco Caccavo and Maria 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.

- Astrea Ocampo, AMELAF
- Rubén Abete, ALIFAR
- Héctor de Orellana, AMID
- Joaquin García Hughes, CANIFARMA
- Julio Ordaz, AMIF
- Patrick Devlyn Jr., CCE
- Yaneth Giha, FIFARMA

Moderator:
- Mario Cimoli, COFEPRIS/UNAM-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

8:00 AM
Participant registration, SRE Building.

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
  - Ana Carolina Moreira Marino Araujo, 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
  - María Antonieta Román Tiburcio, FIFARMA
  - Martin Harvey, EMA

  Moderator:
  José Luis Castro, PAHO/WHO

11:00 AM
Coffee break
11:30 AM
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
y José Luis Castro, PAHO/WHO

1:00 PM
Lunch

Meeting of the PANDHR Steering Committee Members

2:30 PM
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

4:00 PM
Coffee break

4:30 PM
Panel C
Integrated approaches to strengthening regulatory systems: funding, technical assistance, and partnerships
- Danielle Craig, CEPI
- Hitti Sillo, WHO
- Karen de Aquino Noffs, ANVISA (Brazil)
- Leonardo Semprún, EFPIA LATAM Regulatory Network, Rise for Health
Moderator:
Michael Schmitz, USP

Panel B
Clinical trials
- Agustina Bisio, ANMAT (Argentina)
- Carla Sáenz, PAHO/WHO
- Francisca Rodríguez, FIFARMA
- TBC, FDA (United States of America)
Moderator:
Patricia Saidaón, PAHO/WHO

5:00 PM
Panel D
Post-marketing surveillance
- Diana González, FIFARMA
- Miriam Loera, COFEPRIS (Mexico)
- Naiffer Romero, USP (United States of America)
- Romina Viñas, ANMAT (Argentina)
- Verónica Vergara, ISP (Chile)
Moderator:
Edgard Rojas, PAHO/WHO

6:00 PM
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.

- Alejandro Molina, COFEPRIS (México)
- Joaquim Berenguer Jorret, EMA
- Joe MacDougall, FDA (United States of America)
- Dorian Salinas and Marlon Alvarado, ARSA (Honduras)
- 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
- María 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, and closing with a commemorative stamp of the 11th CPANDRH

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

End of the Conference