

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

Report of the Secretariat, current situation, and prospects.

Objectives of the XI Conference.

- Judit Rius Sanjuan, Director, IMT Department, PAHO/WHO
- María 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 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.

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

Moderator:

Mario Cimoli, COFEPRIS/UNAM-X

4:15 PM
(30')

Coffee break

4:45 PM
(75')

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

(150')

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 Giovanni García Iraheta, DNM (El Salvador)
- 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 Daniel Peña, PAHO/WHO

11:00 AM

Coffee break

11:30 AM
(90')

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

Panel B Clinical trials

- Agustina Bisio, ANMAT (Argentina)
- Carla Sáenz, PAHO/WHO
- Francisca Rodríguez, FIFARMA
- TBC, FDA (United States of America)

Moderator:

Patricia Saidón, PAHO/WHO

1:00 PM
(90')

Lunch

Meeting of the PANDHR Steering Committee
Members

2:30 PM
(90')

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
(30')

Coffee break

4:30 PM
(90')

Panel C Integrated approaches to strengthening regulatory systems: funding, technical assistance, and partnerships

- Danielle Craig, CEPI
- Hiiti Sillo, WHO
- Karen de Aquino Noffs, 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

6:00 PM

Day 2 Wrap-up

Day 3

23 August 2024

8:00 AM Participant registration, SRE Building.

8:30 AM
(90')

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
(30')

Coffee break

10:30 AM
(60')

Plenary session 7

Digitization for more efficient regulatory processes.

- Alexandro Molina, COFEPRIS (México)
- Joaquim Berenguer Jornet, 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
(60')

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
(90')

Lunch

2:00 PM
(60')

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

3:00 PM
(60')

Conclusions, adoption of recommendations, and closing with a commemorative stamp of the 11th CPANDRH

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

4:00 PM

End of the Conference