VIII Conference of the Pan American Network on Drug Regulatory Harmonization (CPANDRH), Mexico City.

Regulatory Convergence for Universal Health

Building Capacity, Expanding Access and Facilitating Regulatory Cooperation in the Region of the Americas.

Date: October 19th-21st 2016

Venue: Secretaría de Relaciones Exteriores- SRE (Ministry of Foreign Affairs of Mexico), José María Morelos y Pavón Room, 1st Floor, Plaza Juárez Nº 20, Colonia Centro, Delegación Cuauhtémoc, Mexico City.

PRE REGISTRATION **October 18th 18:00-20:00**	
Hotel Krystal, 1st Floor. Venue: Paseo de la Reforma No.1, Colonia Tabacalera, Delegación Cuauhtémoc, Mexico City.	
Day 1. October 19th	
7:30	**Registration** Secretaría de Relaciones Exteriores, main entrance.
8:30	**Opening ceremony:** **Welcome video** *- Dr. Carissa Etienne, PAHO/WHO Director* *Julio Sánchez y Tépoz, Federal Commissioner for Protection against Sanitary Risks (COFEPRIS)* *Gerry Eijkemans, PAHO/WHO Representative Mexico* *Mikel Arriola, General Director of* Mexican *Social Security Institute (IMSS)* **The role of regulatory systems for medicines and other health technologies in Universal Health** *(James Fitzgerald – PAHO/WHO HSS Director)* *José Narro Robles, Mexico Secretary of Health*
9:30	**PANDRH Secretariat Report:** Update and progress since the VII Conference regarding implementation of the PANDRH Strategic Plan 2014-2020; Objectives of the VIII Conference *(Analía Porrás, PAHO/WHO)*
10:00	**Thematic Session 1: Harmonization , convergence, cooperation and exchange of experiences, and reliance** *Moderators:* *Julio Sánchez y Tépoz, Cofepris – Mexico* *Andrea Grimes, Ministry of Health – Trinidad & Tobago* **Presentation - PANDRH Secretariat: The role of harmonization, convergence and reliance on the development and strengthening of regulatory systems in the Americas.** **Tools and standards** • Opportunities for the adoption of common standards *(Maria Luz Pombo, PAHO/WHO)*

	• Partner and donors: Bill and Melinda Gates Foundation *(Murray Lumpkin, BMG Foundation)* • Short Case Study: Implementation of the International Standards Organization (ISO) for the Identification of Medical Products (IDMP) *(Joan Blair, FDA, USA)* • The benefits of convergence with international standards *(Jaime Oliveira, BAYER|FIFARMA)* DEBATE
11:00	Coffee break
11:30	**Thematic Session 1: Harmonization , convergence, cooperation and exchange of experiences, and reliance** *Moderators:* *Maryam Hinds, Barbados Drug Service* *Beatriz Luna, Ministerio de Salud Pública de Uruguay* **Reliance to strengthen regulatory systems** • National experiences: El Salvador *(José Vicente Coto, DNM)* • International experiences: IMDRF, MDSAP and REPS *(Fabio Pereira Quintino, ANVISA, Brazil)* IGDRP (*Mariana Gebara-Coghlan, TGA, Australia*) ICH (*Lenita Lindström-Gommers, ICH*) DEBATE
12:45	**Thematic Session 2: Core regulatory functions and innovative operating models** *Moderators* *María Angélica Sánchez, INVIMA* *Vanria Rolle, Director Bahamas National Drug Agency* • The role of the evaluation tool in implementing core regulatory functions *(José Peña, PAHO/WHO)* • Caribbean Regulatory System CARPHA perspective *(Lucette Cargil, Caribbean Public Health Agency)* Country perspective: Suriname (*Miriam Naarendorp, Ministry of Health Suriname*) • Pacific Alliance *(Biby Ferrada, ISP, Chile)* DEBATE
13:30	Lunch
13:30 - 14:30	**PANDRH Steering Committee Meeting Lunch** **(Private Meeting - Room "Benito Juárez", 1st floor)**

<table>
<tr><td>14:30</td><td colspan="2">Discussion Groups

Objective: discussion and recommendations of the concept presentations TS1 & TS2 (for the consideration of the Conference)

Moderation, questions , summary
Catherine Parker, BGTD, Health Canada / Juan Carlos Gallaga, COFEPRIS, Mexico
Dulce María Martínez, CECMED, Cuba / Maria Angélica Sánchez, INVIMA, Colombia

*Important note: for this session, the rooms will be split</td></tr>
<tr><td>15:45</td><td colspan="2">PANELS – priority themes</td></tr>
<tr><td></td><td>PANEL A: MEDICAL DEVICES
(Section C – José María Morelos Room)
• Overview of the Medical Devices regulation in the Region of the Americas (Dulce María Martínez, CECMED, Cuba)
• The implementation of technovigilance in the Region (Elkin Hernán Otálvaro Cifuentes – INVIMA, Colombia)
• Short case study: the risk-based regulation of medical devices in Mexico (Rocío Alatorre, COFEPRIS, Mexico)
DEBATE
Moderator: Alexandre Lemgruber, PAHO/WHO</td><td>PANEL B: ACCESS AND RATIONAL USE
(Sections AB - José María Morelos Room)

The role of the regulation in the access and rational use of medicines
• OTC: control of places and conditions of sale (Sebastián Duarte, ANMAT, Argentina)
• The strategy against antimicrobials resistance: the regulation of antibiotics
Brazil short case study (Christiane Santiago Maia, ANVISA)
El Salvador short case study (José Vicente Coto, DNM, El Salvador)

DEBATE
Moderator: José Luis Castro, PAHO/WHO</td></tr>
<tr><td>16:45</td><td colspan="2">Coffee break</td></tr>
<tr><td>17:15</td><td>PANEL C: MEDICAL PRODUCTS OF HUMAN ORIGIN AND OTHER BIOLOGICALS
(Section C – José María Morelos Room)

• Participation of different actors in the regulation of some health technologies: Blood and blood products : the regulatory plurality
Ariel Arias, Health Canada;
Joao Batista da Silva Junior, ANVISA, Brazil
• Gene therapy and cell therapy: regulation challenges faced by NRAs
Maria Teresa Ibarz, INHRR, Venezuela
Joao Batista da Silva Junior, ANVISA, Brazil

DEBATE
Moderator: Maria Luz Pombo, PAHO/WHO</td><td>PANEL D: POST-MARKET SURVEILLANCE
(Sections AB - José María Morelos Room)

• Traceability systems (María José Sánchez, ANMAT, Argentina)
• Pharmacovigilance in the Region:
- periodic safety update report
- active pharmacovigilance
- market withdrawal of medications
(Juan Roldón, ISP, Chile)
• Successful experiences in coordination with public health programs (Lazaro Eduardo Avila Berumen, Cofepris, Mexico)
• The implementation of REDMA Exchange Program in Medical Device Reports from RNAs of the Region of the Americas (Dulce María Martínez, CECMED, Cuba)

DEBATE
Moderator: José Luis Castro, PAHO/WHO</td></tr>
<tr><td>18:15</td><td colspan="2">Official photo – Main Stairs of the Ministry of Foreign Affairs</td></tr>
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	& Reception – Terrace of the Ministry of Foreign Affairs (2nd floor)
Day 2, October 20th	
8:00	Private session for NRAs: • Harmonization of regulatory capacity assessment tool (*Samvel Azatyan, WHO*) • Regional cooperation initiatives: mechanisms for better coordination *(José Peña, PAHO/WHO)* DEBATE
9:30	**Thematic Session 3: Competence in good regulatory practices and regulatory science** *Moderators:* *Catherine Parker, Biologics and Genetic Therapies – Health Canada* *Maria Auxiliadora Vargas de Dentice, Dirección Nacional de Vigilancia Sanitaria - Paraguay* **Cooperative models between regulator and regulated stakeholders** • Pharmaceutical perspectives *Alfredo Antia, ALIFAR* *Alexis José Serlin, CANIFARMA* • National experiences : Periodic meetings & regulatory education for industry *(Patricia Pineda, FDA, USA)* Cuba short case *(Dulce María Martínez, CECMED, Cuba)* • International experiences The European Medicines Agency (*Riccardo Luigetti, EMA*) Agencia Española de Medicamentos y Productos Sanitarios (*Belén Crespo Sánchez-Eznarriaga, AEMPS*) DEBATE
11:00	Coffee break
11:30	**Thematic Session 3: Competence in good regulatory practices and regulatory science** *Moderators:* *Edmundo Garcia, FDA, USA* *Beatriz Eugenia Batrez Rivera, Ministerio de Salud Pública y Asistencia Social – Guatemala* **Presentation – PANDRH Secretariat: Adoption and implementation of prioritization model for PANDRH operation** *(Murilo Freitas Dias, PAHO/WHO)* • Global regulatory curriculum *(Silvia Bendiner, RAPS)* Cooperation between academy / regulatory authority in training (capacity building) models *(Maria Teresa Ibarz, INHRR, Venezuela)* • Centers of Excellence (*Samvel Azatyan, WHO*) DEBATE
13:30	Lunch
14:30	**Discussion Groups TS3** Objective: discussion and recommendations for the concept note TS3 (for the consideration of the conference) *Moderators* (*guide questions & summary):* *Edmundo Garcia, FDA / Mario Alanis – COFEPRIS, Mexico* *Cammilla Horta – ANVISA / Philip Budashewitz, FDA, USA*

	*Important note: for this session, the rooms will be split	
15:45	**PANEL E: QUALITY MANAGEMENT (Sections AB - José María Morelos Room)** Quality Management Systems (QMS): • NRA perspectives *Pablo Ortíz (ISP, Chile)* *Dalia Castillo(MoH, Dominican Republic)* • Industry perspectives *Gilfredo Navarro (J&J |FIFARMA)* *Elmer Torres (ALIFAR)* DEBATE Moderator: *Murilo Freitas, PAHO/WHO*	**PANEL F: EMERGENCY PREPAREDNESS natural disasters, epidemiological emergencies (Section C – José María Morelos Room)** • International mobilization: public health emergencies of international importance (H1N1 , Zika) *(Patricia Oliveira Pereira Tagliari, ANVISA, Brazil)* • Regulatory approval and health technology granted in emergencies and special situations: case presentation (drugs, vaccines and clinical trials) *Pamela Milla, ISP – Chile* *Patricio Ocampo, Agencia Nacional de Regulación, Control y Vigilancia Sanitaria - Ecuador* DEBATE Moderator: *Jose Peña, PAHO/WHO*
16:45	Coffee break	
17:15	**Rapporteurs discussion groups' session**	
18:30	Closing of the day	
	Day 3. October 21st	
8:00	**Thematic Session 4: Investment Case for Regulatory Systems Strengthening** *Moderators:* *Patricia Oliveira Pereira Tagliari, ANVISA, Brazil* *Danini Contreras, Ministry of Health – Belize* • Generics: the added value of incorporation into the health system *(Julio Sánchez y Tépoz, COFEPRIS)* • Falsified drugs : the cost to health systems *(María José Sánchez, ANMAT, Argentina)* • PDUFA | GDUFA *(Khyati Roberts, AbbVie|FIFARMA)* • Health surveillance model: a risk-based approach – IVC SOA *(Elkin Hernán Otálvaro Cifuentes – INVIMA, Colombia)* DEBATE	
9:30	Conclusions and adoption of the recommendations of the VIII CPARF	
10:00	Closing of the Conference	