IX Pan American Network for Drug Regulatory Harmonization Conference (CPANDRH)

San Salvador, El Salvador

24 to 26 October 2018

"Regulatory Harmonization Contributions to the Achievement of Health for All"

Commemorating 20 years of PANDRH and 40 years of ALMA ATA

Venue: Sheraton Presidente San Salvador Hotel

PRE- REGISTRATION **23 October: 18:00-20:00**		
Registration *(Sheraton Presidente San Salvador Hotel)*		
Day 1 24 October		
7:30	**Registration**	
Room: Presidente 1 & 2		
8:00 – 9:00	**Opening Ceremony** - *Greetings words. Reina Morales de Acosta, Dirección Nacional de Medicamentos* - *Allusive words. Dr. Jarbas Barbosa, PAHO/WHO*	
9:00 – 10:00	**The role of regulators in the implementation of Alma-Ata towards Universal Health** - From Alma-Ata towards Universal Health: the regulatory systems and their role in the achievement of Alma-Ata goals *(Jarbas Barbosa, PAHO/WHO)* - *20 years of PANDRH: A brief history of the regulatory network (video)*	
10:00 – 10:30	**Coffee - Break**	
10:30 – 11:00	**PANDRH Secretariat Report:** - Update and progress since the VIII Conference regarding implementation of the PANDRH Strategic Plan 2014-2020 and objectives of the IX Conference *(Analía Porrás, PAHO/WHO)*	
11:00 – 12:30	**Plenary 1: *The regulation in promoting Universal health access and coverage*** **Moderator/Facilitator:** *Virginia Asin-Oostburg (CARPHA), Julio Sánchez y Tépoz (COFEPRIS)* - The impact of RSS global in improving access to essential medicines and other health technologies *(Emer Cooke, WHO)* - Reliance and strengthening of regulatory systems: the EMA and Article 58 *(Martin Harvey, EMA)* - The health system reform in El Salvador: Creation of the National Drug Directorate of El Salvador *(Reina Morales de Acosta, DNM)* DEBATE	
12:30-14:00	**Lunch**	**Closed meeting CARICOM-PAHO**

<table>
<tr><th colspan="3">Room: Presidente 1 y 2</th></tr>
<tr><td>14:00 – 15:30</td><td colspan="2">Plenary 2: Critical regulatory challenges and gaps
Moderator/Facilitator: Ariel Arias (Health Canada), Rafaél Pérez Cristiá (CECMED)

- Advanced therapies as medical products: advances in regulation, challenges and international initiatives (Wilson Bryan, CBER/FDA)
- Challenges in the regulation of cell therapy products: The Regional situation and recommendations (Mauricio Beltrán, PAHO/WHO)

DEBATE</td></tr>
<tr><td>15:30 – 15:45</td><td colspan="2">Coffee - Break</td></tr>
<tr><td>15:45 – 17:15</td><td colspan="2">Plenary 3: Benchmarking and regulatory efficiency
Moderators/ Facilitator: Patricia Tagliari (ANVISA), Gopa Raychaudhuri (CBER/FDA)

- Development and implementation of the global tool of evaluation of regulatory systems (GBT) and its links with the regional RSS programs: strengthening regulatory systems, promoting convergence. Alireza Khadem (WHO)
- Reliance: from theory to practice
▪ Its use in regulatory decisions: GMP (Francisco Sierra Esteban, INVIMA)
▪ Its use in regulatory decisions: bioequivalence (Isabel Sánchez, ISP)
- Principles of “reliance”: conceptual note and recommendations (Analía Porrás, PAHO/WHO)

DEBATE</td></tr>
<tr><td rowspan="2">17:15 – 18:45</td><td>Room: Presidente 1 y 2</td><td>Room: Presidente 3</td></tr>
<tr><td>Discussion/ recommendations of adoption
Principles of “reliance”: conceptual note and recommendations

Moderators/ Rapporteurs: Patricia Tagliari (ANVISA), Gracia Wheatley-Smith (British Virgin Islands)</td><td>Discussion/ recommendations of adoption
Critical regulatory challenges and gaps in products for advanced therapies.

Moderators/ Rapporteurs: Wilson Bryan (US FDA), Giusele Rodríguez Hernández (Costa Rica)</td></tr>
<tr><td>18:45</td><td colspan="2">Welcome Reception</td></tr>
</table>

<table>
<tr><th colspan="3">Day 2
25 October</th></tr>
<tr><td colspan="3">Room: Presidente 3</td></tr>
<tr><td>8:00 – 9:00</td><td colspan="2">Closed Session for NRA of reference, PAHO and WHO
Notes: this meeting will not have simultaneous interpretation service.</td></tr>
<tr><td colspan="3">Room Presidente 1 y 2</td></tr>
<tr><td>9:00 – 10:30</td><td colspan="2">Plenary 4: Transparency and information for decision making
Moderators/ Facilitator: Oneil Atkins (Guyana), Julio Sánchez y Tépoz (COFEPRIS)

- Transparency, responsibility and participation in regulatory processes: the interrelation of the industry with the regulator:
o Rubén Abete (ALIFAR)
o Cristina Mota Pina (FIFARMA)
- The importance of multi stakeholder’s networks for the prevention, detection and response to substandard quality medicines (Cammilla Horta, ANVISA)
- Engaging media and citizens/ health risk communication and consumer education (Reina Morales de Acosta, DNM)

DEBATE</td></tr>
<tr><td>10:30 – 11:00</td><td colspan="2">Coffee – break</td></tr>
<tr><td rowspan="2">11:00 – 12:00</td><td>Room Presidente 1 y 2</td><td>Room Presidente 3</td></tr>
<tr><td>Panel A

Antimicrobial resistance and regulatory enforcement

- PANDRH project update: access and antimicrobial resistance (DNM, El Salvador)
- Interaction between the regulatory authorities and those responsible for animal health (Enrique Pérez, PAHO/WHO)
- Development of National Programs of AMR (Pilar Ramon, PAHO/WHO)

DEBATE
Moderator/Facilitator: Isabel Sánchez (ISP), José Luis Castro (PAHO/WHO)</td><td>Panel B

Regulatory aspects for Cannabis medicinal use

Countries’ experiences:
- Uruguay (Isabel Slepak)
- Jamaica (Cynthia Lewis)
- Colombia (Francisco Sierra Esteban)
- Mexico (Julio Sánchez y Tépoz)

DEBATE
Moderator/Facilitator: Ana Gabriela Silva Flor de Olorteguiy (DIGEMID), José D. Peña (PAHO/WHO)</td></tr>
<tr><td>12:00 – 13:30</td><td>Lunch</td><td>PANDRH Steering Committee Meeting Lunch</td></tr>
</table>

<table>
<tr><td colspan="3">Room: Presidente 1 & 2</td></tr>
<tr><td>13:30 – 15:00</td><td colspan="2">Plenary 5: Improving regulatory capacities
Moderator/Facilitator: Reina Morales de Acosta (DNM), Vinoj Sewberath Misser (Surinam)

- Regulatory System Strengthening in the Region: the industry perspective
▪ Alfredo Antía (ALIFAR)
▪ Thomas Schreitmueller (FIFARMA)
- Sub-regional and other international experiences: regulatory systems achievements / challenges
▪ Central American integration mechanism (Marta Rosales Granera, Nicaragua)
▪ Caribbean Regulatory System: adopting recommendations from the CRS (Virginia Asin-Oostburg, CARPHA)
▪ Improving regulatory capacities: multi-national assessment teams that focus on engaging smaller authorities and EU-Network Training Centre initiative (Martin Harvey, EMA)
- Concept note: regulatory systems models for small markets / states with limited resources (Charles Preston, PAHO/WHO)

DEBATE</td></tr>
<tr><td>15:00 - 16:00</td><td colspan="2">Discussion and recommendations of the Concept Note: regulatory systems models for small markets/ countries with limited resources
Moderator and Rapporteur: Gina Anoushka Karine Archer (Bahamas), Christal Samouge (Belize)</td></tr>
<tr><td>16:00 – 16:15</td><td colspan="2">Coffee - break</td></tr>
<tr><td rowspan="2">16:15 – 17:15</td><td>Room Presidente 1 y 2</td><td>Room Presidente 3</td></tr>
<tr><td>Panel C
Current challenges in medical devices regulation in the Region

- PANDRH Project update: Strengthening the regulatory capabilities of Medical Devices (Rafaél Pérez Cristiá, CECMED)
- Reuse of medical devices: how to regulate it? (Elkyn Otálvaro Cifuentes, INVIMA)
- Personalized medical products (Marcela Claudia Rizzo, ANMAT)

DEBATE
Moderator/Facilitator: Juan Carlos Galarza (ARCSA), Alexandre Lemgruber (PAHO/WHO)</td><td>Panel D
Regional advances and international lessons in the regulation of biologics

- PANDRH Project update: Biologics forum (Patricia Aprea, ANMAT)
- Training offers (Virtual Campus of Public Health - sanitary regulation of biological and biotechnological products (Maria T. Ibarz, PAHO/WHO)

DEBATE
Moderator/Facilitator: Alexandra Hernández (INHRR), María Luz Pombo (PAHO/WHO)</td></tr>
<tr><td>17:15 – 18:30</td><td colspan="2">Room Presidente 1 y 2

Plenary 6: The use of information in regulatory convergence
Moderator/Facilitator: Lourdes Rivaldi (DNVS), Murilo Freitas Dias (PAHO/WHO)

- Participation in global harmonization initiatives (Rafaél Pérez Cristiá, CECMED)
- PANDRH project: advances in the exchange of information in the Region of the Americas on global regulatory convergence initiatives - Presentation of the outcomes (Ariel Arias, Health Canada)
- Transparency and information for decision making: publication of clinical data and patient engagement (Martin Harvey, EMA)
- Platforms for promoting the exchange of information between regulators: REPs-RISE, REPs-MDSAP, PRAIS, REDMA (Fernanda Lessa, PAHO/WHO)</td></tr>
</table>

	DEBATE
18:30	**End of the activities**

Day 3 26 October		
	Room Presidente 1 & 2	**Room Presidente 3**
9:00 – 10:30	**Panel E** ***Regulating supply chain and its impact in Health Systems*** - PANDRH Project update: assessing CPP requirement for medicines registration *(Jaime Oliveira, FIFARMA)* - Role of regulation in the supply chain *(Isabel Sánchez, ISP)* - Interrelationship of supply chain-access and rational use: country experience *(Oneil Atkins, Guyana)* DEBATE **Moderador/Facilitator:** *Cynthia Lewis (Jamaica), Murilo Freitas (OPS/OMS)*	**Panel F** ***OTC medicines and regulation*** - PANDRH Project update: from the traditional model to the new scenarios of regulatory feedback: the non-prescription medicines *(Sebastián Rami Fernández, ANMAT)* - Challenges in the regulation of internet medicines sales *(*Mario González, *DNM)* - National experience: publication of OTC lists *(Christal Samouge, Belize)* DEBATE **Moderador/Facilitator:** *Francis Contreras (Honduras), José Luis Castro (PAHO/WHO)*
10:30 – 11:00	**Coffee break**	
Room: Presitente 1 & 2		

11:00 – 12:30	**Plenary 7: *Risk based regulatory approaches across regulatory functions***
	Moderator/ Facilitator: Caroline Díaz Espinoza *(DIGEMAPS), Lizbeth Tristán (Panamá)*
	
	- Risk Management for regulatory practices:
	  ▪ *Denise Bonamici (FIFARMA)*
	  ▪ *Carmen Estela Pérez (ALIFAR)*
	- Risk based criteria applied to regulatory inspections *(Francisco Sierra Esteban, INVIMA)*
	- Rethinking the use of quality control laboratories *(Beatriz Clara, DNM)*
	- PANDRH project update: joint evaluation of periodic safety update reports (PSURs), risk management plans (RMPs), and periodic benefit-risk evaluation reports (PBRERs) *(Isabel Sánchez, ISP)*
	
	DEBATE	

12:30 – 14:00	**Conclusions and adoption of the recommendations of the IX PANDRH Conference**	
14:00	Closing Remarks – Distribution of participation certificates	