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** - *Country's authorities and representatives* - *PAHO/WHO Representatives*	
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 (TBD) - *20 years of PANDRH: A brief history of the regulatory network (video)*	
10:10 – 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:** *CARPHA/Mexico* - 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 (EMA, to be defined) - The health system reform in El Salvador: Creation of the National Drug Directorate of El Salvador (El Salvador) DEBATE	
12:30-14:00	**Lunch**	**PANDRH Steering Committee Meeting Lunch** **(**Private Meeting - Room Presidente 3**)**

<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: Canada, Cuba

- Advanced therapies: advances in regulation, challenges and international initiatives (US FDA-IPRP)
- Medical devices: advances in the regulation of personalized medicine (Argentina)
- 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: Brazil, Argentina

- 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. (WHO)
- Reliance: from theory to practice
▪ MDSAP initiative (Canada)
▪ Use of regulatory decisions of others: GMP (Colombia)
- Principles of “reliance”: conceptual note and recommendations (WHO, PAHO)

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: Colombia, Mexico</td><td>Discussion/ recommendations of adoption
Critical regulatory challenges and gaps in products for advanced therapies.
Moderators/ Rapporteurs: United States, Argentina</td></tr>
<tr><td>18:45</td><td colspan="2">Official photo – TBD.
&
Reception – TBD.</td></tr>
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<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: Guyana, El Salvador

- Transparency, responsibility and participation in regulatory processes: the interrelation of the industry with the regulator (ALIFAR)
- Transparency, responsibility and participation in regulatory processes: the interrelation of the industry with the regulator (FIFARMA)
- The importance of multi stakeholder’s networks for the prevention, detection and response to substandard quality medicines (Brazil)
- Engaging media and citizens/ health risk communication and consumer education (Mexico)

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<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 - Presentation of the outcomes (PAHO/ WHO, Country)
- Interaction between the regulatory authorities and those responsible for animal health (TBD)
- Country experiences: control of the prescription (TBD)

DEBATE
Moderator/Facilitator: Chile and PAHO (José Luis Castro)</td><td>Panel B

Regulatory aspects for Cannabis medicinal use

- Countries’ experiences:
▪ Chile
▪ Uruguay
▪ Jamaica
▪ Colombia or Mexico

DEBATE
Moderator/Facilitator: Uruguay and PAHO (José D. Peña)</td></tr>
<tr><td>12:00 – 13:30</td><td>Lunch</td><td>Closed meeting CARICOM-PAHO
Venue: Room Presidente 3</td></tr>
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<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: El Salvador, Suriname

- RSS in the Region: the industry perspective
▪ ALIFAR
▪ FIFARMA
- Sub-regional experiences: regulatory systems achievements / challenges
▪ Central American integration mechanism (Nicaragua)
▪ Caribbean Regulatory System: adopting recommendations from the CRS (Guyana)
- Concept note: regulatory systems models for small markets / countries with limited resources (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: Bahamas, 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: Strengthening the regulatory capabilities of Medical Devices - Presentation of outcomes (Cuba)
- Reuse of medical devices: how to regulate it? (Colombia)
- Software as a medical device (TBD)

DEBATE
Moderator/Facilitator: Colombia and PAHO (Alexandre Lemgruber)</td><td>Panel D
Regional advances and international lessons in the regulation of biologics

- PANDRH project: biologics forum – Presentation the outcomes (Argentina):
▪ Training offers (Virtual Campus of Public Health - sanitary regulation of biological and biotechnological products (Maria T. Ibarz – academic coordinator)
- Blood products: blood and blood products services (Chile)

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Moderator/Facilitator: Venezuela and PAHO (Mauricio Beltran/ María Luz Pombo)</td></tr>
<tr><td rowspan="2">17:15 – 18:30</td><td colspan="2">Room Presidente 1 y 2</td></tr>
<tr><td colspan="2">Plenary 6: The use of information in regulatory convergence
Moderator/Facilitator: Ecuador, Colombia

- Participation in global harmonization initiatives (Cuba)
- PANDRH project: advances in the exchange of information in the Region of the Americas on global regulatory convergence initiatives - Presentation of the outcomes (TBD by project's coordinators)
- Platforms for promoting the exchange of information between regulators: REPs-RISE, REPs-MDSAP, PRAIS, REDMA. (PAHO)

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<tr><td>18:30</td><td colspan="2">End of the activities</td></tr>
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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 – presentation of the outcomes *(FIFARMA)* - Role of regulation in the supply chain *(Ecuador)* - Interrelationship of supply chain-access and rational use: country experience *(Guyana)* DEBATE **Moderador/Facilitator:** Jamaica and PAHO (*Murilo Freitas)*	**Panel F** ***OTC medicines and regulation*** - From the traditional model to the new scenarios of regulatory feedback: updates of the non-prescription medicines PANDRH project *(ANMAT)* - Challenges in the regulation of internet medicines sales *(El Salvador)* - National experience: publication of OTC lists *(Belize)* DEBATE **Moderador/Facilitator:** Honduras and PAHO (*José Luis Castro)*
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:** Paraguay, USA - Risk Based Approaches for licensing Medical Devices (Canada) - Risk Management for regulatory practices: ▪ FIFARMA ▪ ALIFAR - Risk based criteria applied to regulatory inspections (Colombia) - Rethinking the use of quality control laboratories (Panama) **DEBATE**	
12:30 – 14:00	**Conclusions and adoption of the recommendations of the IX PANDRH Conference**	
14:00	Closing Remarks – Distribution of participation certificates	