VII Conference of the Pan American Network for Drug Regulatory Harmonization

AGENDA

Sixteen Years Promoting Good Regulatory Practices in the Region of the Americas

5-7 September 2013, Delta Ottawa City Centre, Ottawa, Canada

5 September 2013 (Day 1)			
Registration (8:30 – 9:00) All Day in Ballroom A & B			
9:00	**Opening Ceremony** *9:00-9:05 Health Canada representative on PANDRH Steering Committee, Mike Ward, to welcome participants and introduce Health Canada's Assistant Deputy Minister of Health Products and Food Branch (HPFB), PAHO's Assistant Director, and WHO Director of Essential Medicines and Health Products* *9:05-9:15 Opening remarks Assistant Deputy Minister of HPFB, Health Canada - Kathryn McDade* *9:15-9:25 Opening remarks Assistant Director, PAHO - Luiz A. Galvao* *9:25-9:35 Opening remarks Director of Essential Medicines and Health Products, WHO - Kees de Joncheere* **Regional context, lessons learned and rationale for the PANDRH Strategic Development Plan 2014-2020** *[James Fitzgerald - PAHO/WHO]*		
10:00	**Strategic objective 1 (SO): "To promote effective governance of PANDRH and active participation of NRAs towards regulatory convergence and harmonization"** *[Moderators: Mexico, Canada]* *Introductory presentations:* A **-** Governance models of other networks. Lessons learned from ICH, APEC, IMDRF and EMA *[Speakers: Michelle Limoli – US FDA, Mike Ward - Health Canada, and Alexios Skarlatos - EMA]* B - WHO support to the establishment of the AMRH Initiative *[Speaker: Samvel Azatyan -WHO]*		
Coffee and Tea Break: Poster Session (11:00 - 11:30) Joliet Salon and Ballroom Foyer			
11:30	**Ballroom A** **Working Group 1** **Group moderator: Mexico**	**Richelieu/Frontenac Salon** **Working Group 2** **Group moderator: Canada**	**Ballroom B** **Working Group 3** **Group moderator: Cuba**
	12:30 – 13:00 Plenary Discussion: Strategic Objective 1- conclusions and recommendations *[MEX, CAN, CUB]*		
LUNCH (13:00 – 14:00)			
14:00	**Strategic objective 2: " Defining priorities, strategies and mechanisms for regulatory convergence and harmonization, and supporting their dissemination, adoption and implementation by NRAs"** *[Moderators: Brazil, United States of America]* *Introductory presentations :* A- Overview of regulatory capacity and NRA priorities based on PRAIS data and NRA surveys *[Speaker: Murilo Freitas –PAHO/WHO]* B- The objectives and development of the joint assessment tool for evaluation of NRA functionality *[Speaker: David Wood -WHO]*		
Coffee and Tea Break: Poster Session (15:00 – 15:30) Joliet Salon and Ballroom Foyer			
15:30	**Ballroom A** **Working Group 1** **Group moderator: Brazil**	**Richelieu/Frontenac Salon** **Working Group 2** **Group moderator: United States**	**Ballroom B** **Working Group 3** **Group moderator: Colombia**
	16:30 – 17:00 Plenary Discussion: Strategic Objective 2- conclusions and recommendations *[BRA, USA, COL]*		
GROUP PHOTO Ballroom Foyer			
NETWORKING – COCKTAIL RECEPTION (18:00 – 21:00) **Pinnacle/Panorama Salon**			

Pan American Health Organization / World Health Organization Americas · 110 1902 - 2012 · PANDRH RED PARF · ALIFAR · FIFARMA · Government of Canada / Gouvernement du Canada

AGENDA

Sixteen Years Promoting
Good Regulatory Practices in the Region of the Americas

5-7 September 2013, Delta Ottawa City Centre, Ottawa, Canada

<table>
<tr><th colspan="4">6 September 2013 (Day 2)</th></tr>
<tr><td colspan="4">8:30-13:00 in Ballroom A & B</td></tr>
<tr><td>8:30</td><td colspan="3">Strategic objective 3: "To promote the strengthening of competencies in Good Regulatory Practices and Regulatory Science" [Moderators: El Salvador, Peru]

Introductory presentations:
A- Good Regulatory Practices [Speaker: COFEPRIS as a representative of the Regional Reference NRAs]
B- Approaches to apply regulatory science and the development of regulatory curricula [Speaker: Mary Lou Valdez and Carl Sciacchitano - US FDA]
C- Implementing Good Regulatory Practices through evaluation of regulatory capacity [Speaker: Miriam Aimée Naarendorp – NRA Suriname]</td></tr>
<tr><td>9:30</td><td>Ballroom A
Working Group 1
Group moderator: El Salvador</td><td>Richelieu/Frontenac Salon
Working Group 2
Group moderator: Peru</td><td>Ballroom B
Working Group 3
Group moderator: Costa Rica</td></tr>
<tr><td colspan="4">Coffee and Tea Break: Poster Session (10:30 – 11:00) Joliet Room and Ballroom Foyer</td></tr>
<tr><td>11:00</td><td colspan="3">11:00-11:25 Plenary Discussion: Strategic Objective 3- conclusions and recommendations [ELS, PER, COR]</td></tr>
<tr><td>11:25</td><td colspan="3">Strategic objective 4: "To promote the exchange of experiences and regulatory knowledge between NRAs inside and outside PANDRH" [Moderators: Argentina, Barbados]

Introductory presentations:
A- Lessons learned from international effective cooperation agreements in relation to regulatory functions (bilateral and sub-regional case studies): [Speaker: CECMED as a representative of the Regional reference NRAs; José V. Coto (El Salvador);and Catherine Parker (Health Canada)]
B- Regulatory information exchange mechanisms: PRAIS and other tools for technical cooperation among countries [Speakers: Analía Porrás (PAHO, Catherine Parker (Health Canada) and José Luis Castro (PAHO)]</td></tr>
<tr><td colspan="4">LUNCH (13:00 – 14:00)</td></tr>
<tr><td colspan="4">14:00 – 15:30: PANDRH Steering Committee meeting - Closed session for members only
Richelieu/Frontenac Salon</td></tr>
<tr><td colspan="4">Coffee and Tea Break: Poster Session (15:30 – 16:00) Joliet Room and Ballroom Foyer</td></tr>
<tr><td colspan="4">THEMATIC SESSIONS</td></tr>
<tr><td>16:00</td><td colspan="2">Richelieu/Frontenac Salon
Pharmacovigilance and patient safety*

[Moderator :José Luis Castro - PAHO/WHO]</td><td rowspan="2">Ballroom A & B
Session on Biotherapeutic Products*

[Moderators: Ivana Knezevic – WHO and Maria Pombo PAHO/WHO]</td></tr>
<tr><td>17:15</td><td colspan="2">Richelieu/Frontenac Salon
Substandard/spurious/falsely-labeled/falsified/counterfeit (SSFFC) medicines: Global and Regional perspectives*

[Moderator: Kees de Joncheere – WHO]</td></tr>
<tr><td colspan="4">Day ends at 18:30</td></tr>
</table>

**Detailed agenda will be presented during the session*

AGENDA

Sixteen Years Promoting
Good Regulatory Practices in the Region of the Americas

5-7 September 2013, Delta Ottawa City Centre, Ottawa, Canada

7 September 2013 (Day 3)	
THEMATIC SESSIONS (continued)	
8:30	**Ballroom A & B** Round Table on Medical Devices Regulation* *[Moderator: Alexandre Lemgruber – PAHO/WHO]* *[Speakers: representatives from the following NRA: ANVISA, CECMED, ANMAT, Health Canada, INVIMA and COFEPRIS]]*
Coffee and Tea Break: Poster Session (10:30 – 11:00) Joliet Room and Ballroom Foyer	
11:00	**Ballroom A & B** Implementation of Bioequivalence Regulation - Case studies* *[Moderator: José Peña – PAHO/WHO]* *[Speakers: representatives from the following NRA: ANMAT, ANVISA, CHILE and COFEPRIS]]*
12:00	Presentations of recommendations from the 7th PANDRH Conference *[Speaker: PANDRH Secretariat]* Special recognition for posters Closing remarks *[Health Canada, WHO, PAHO]*
Attendance Certificates (13:30 – 14:30)	

**Detailed agenda will be presented during the session*