

## AIDE-MEMOIRE

### Meeting: Steering Committee of the Pan American Network for Drug Regulatory Harmonization (PANDRH)

Date: 19<sup>th</sup> and 20<sup>th</sup> October 2016

The Steering Committee (SC) of the Pan American Network for Drug Regulatory Harmonization (PANDRH) met on 19<sup>th</sup> and 20<sup>th</sup> October 2016 during the framework of the 8<sup>th</sup> PANDRH Conference held in Mexico City. The objective of this meeting was to renew its members, in accordance with the new PANDRH governance model, based on PANDRH Statutes<sup>1</sup>, and to define the process for the review and approval of projects presented to the SC. The attendance list is presented below:

Personal attendance		
1.	Sebastián Duarte	ARGENTINA
2.	Anne Vanria Rolle	BAHAMAS
3.	Miriam Hinds	BARBADOS
4.	Patrícia Pereira	BRAZIL
5.	Cammilla Horta	BRAZIL
6.	Ariel Arias	CANADA
7.	Pablo Ortiz	CHILE
8.	Alejandro Salinas	CHILE
9.	Maria Angelica Sanchez Herrera	COLOMBIA
10.	Dulce María Martinez	CUBA
11.	José Vicente Coto	EL SALVADOR
12.	Julio Sánchez	MEXICO
13.	Mario Alanis	MEXICO
14.	Miriam Naarendorp	SURINAME
15.	Maria Auxiliadora Vargas de Dentice	PARAGUAY
16.	Philip Budashewitz	USA
17.	Ana Pineda	USA
18.	Edmundo García	USA
19.	Beatriz Luna	URUGUAY
20.	Maria Teresa Ibarz	VENEZUELA
21.	Esperanza Briceño	VENEZUELA
22.	Alberto Paganelli	FIFARMA
23.	Miguel Maito	ALIFAR
24.	Analia Porras	PAHO

<sup>1</sup> PANDRH Statutes are available from:

[http://www.paho.org/hq/index.php?option=com\\_docman&task=doc\\_download&gid=33717&Itemid=270&language=en](http://www.paho.org/hq/index.php?option=com_docman&task=doc_download&gid=33717&Itemid=270&language=en)

25.	Ana Paula Juca Silva	PAHO
26.	Mariluz Pombo	PAHO
27.	Fernanda Lessa	PAHO
28.	Murilo Freitas	PAHO
29.	Guiselle Rodrigues	COSTA RICA
30.	Lucette Cargill	CARPHA

## I. Renewal of the Steering Committee Members

The table below presents the new Steering Committee (SC) members with mandate until the 9<sup>th</sup> PANDRH Conference:

<b>Subregion</b>	<b>Title</b>	<b>Alternate</b>
North America	CANADA	UNITED STATES
Central America + Cuba + Dominican Republic	EL SALVADOR	COSTA RICA
Caribbean	SURINAME	BAHAMAS
Andean Region	CHILE	COLOMBIA
Southern Cone	ARGENTINA	BRAZIL
Caribbean Regulatory System (CRS)	TBD	TBD
National Regulatory Authority of Regional Reference (NRAR)	TBD	TBD
ALIFAR	Ruben Abete	Miguel Maito
FIFARMA	Alberto Paganelli	Luis Villalba

Representatives from CRS and NRAR are pending definition and were asked to inform the PANDRH Secretariat as soon as they have the nominations.

## II. Process for submission and evaluation of projects

The Steering Committee became aware of the five projects received prior to the Conference and decided to issue comments and questions on the projects by 11 November 2016. The Secretariat will transmit these comments and/or questions received to the proposers. Proposers will have until November 25, 2016 to present answers and make the adjustments that are required to the projects.

Revised and adjusted projects will be sent to the SC members for evaluation and decision at a virtual meeting to be held in the week of December 12, 2016. The SC recommendations should indicate the value added for the Network as well as the activities to be carried out. Once again, it was specified that the projects should respond to the priorities of the Region and meet the criteria defined by the Network in the document "Procedure for Prioritization of Areas and Selection of Projects"<sup>2</sup>

<sup>2</sup> Procedure for Prioritization of Areas and Selection of Projects available from:  
[http://www.paho.org/hq/index.php?option=com\\_docman&task=doc\\_download&gid=33716&Itemid=270&lang=en](http://www.paho.org/hq/index.php?option=com_docman&task=doc_download&gid=33716&Itemid=270&lang=en)



The five projects are listed below:

- *“Network for sharing information in the Americas on global regulatory convergence initiatives”* proposed by ANVISA/Brazil, FDA/USA and HC/Canada.
- *“Non-prescription drugs: From the traditional model to new regulatory feedback scenario”* proposed by ANMAT/Argentina, ANVISA/Brazil, INVIMA/Colombia and COFREPRIS/Mexico
- *“Strengthening of regulatory capacity on medical devices in the Region of the Americas”* proposed by INVIMA/Colombia and CECMED/Cuba.
- *“Development of an online system for the identification of registered drugs in support of post-marketing surveillance and the struggle against counterfeit, fraudulent, and contraband medicines in the Republic of Colombia and the Bolivarian Republic of Venezuela”* proposed by INVIMA/Colombia and INRHH/Venezuela.
- *“Creation of a Distance Learning platform for professionals in the national regulatory authorities (NRAs) of the Region of the Americas”* proposed by Instituto Racine/Brazil.

### III. Call for new Projects

New projects are going to be accepted starting on 1 January 2017. New proposals will be presented to the SC for evaluation and recommendation in the semester after the receipt of the projects. Nonetheless, this procedure will have to be deeply discussed during the next SC meeting. The Secretariat is in charge of presenting a process flow for new projects' submission by the next SC meeting.

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