PAHO Update

Pan American Health Organization

World Health Organization

REGIONAL OFFICE FOR THE Americas

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IMDRF Meeting

Ottawa, Canada

September 2017

Regional Working Group on Medical Device Regulation

- **Established:** July, 2012 with 12 member countries; currently with 20
- **New members**: Bolivia, Jamaica, Nicaragua and Trinidad&Tobago
- **Objective:** To Strengthen the Regulatory capacity for Medical Devices in the Region of the Americas.

Argentina	Bolivia	Brazil	Canada
Chile	Colombia	Costa Rica	Cuba
Dominican Republic	Ecuador	El Salvador	Honduras
Jamaica	Mexico	Nicaragua	Panama
Paraguay	Peru	Trinidad & Tobago	Uruguay

Regional Meetings

- ✓ **6 Regional Annual Meetings: Cuba (2012), Argentina (2013), USA (2014), Colombia (2015), Brazil (2016) and Mexico (2016)**

- ✓ **Last Regional Meeting: October 2016 - Mexico City (hosted by COFEPRIS)**
  - In conjunction with the PANDRH meeting

- ✓ **VII Regional Meeting: 21-22 September 2017 - Ottawa (hosted by Health Canada)**
  - 3rd Regional meeting in conjunction with the IMDRF meeting
  - 21 September: open session
  - 22 September: regulators only
  - 26 representatives from 18 countries are participating in the IMDRF Stakeholder Forum and in the Regional Meeting
  - Representatives from 4 regulatory authorities (ANMAT-Argentina, CECMED-Cuba, COFEPRIS-Mexico and INVIMA-Colombia) participated as observers in the Executive Management Committee

Collaboration with IMDRF

	TOPIC	SECRETARIAT	ACTIVITIES
Mirror Working Groups	REDMA Program (NCAR)	**Cuba (CECMED)** Brazil (ANVISA) Colombia (INVIMA)	➢ Operation and procedures documents of the REDMA Program ➢ Technical Meeting in Havana (2016) ➢ Virtual Training Course ➢ Software development for the REDMA Program - *REDMA Web System;* pilot activity with 10 countries
	Software as medical devices	**ANMAT (Argentina)** CECMED (Cuba) COFEPRIS (Mexico) MoH (Uruguay)	➢ Questionnaire for the analysis of the current regulatory situation in the Region ➢ Feedback from 8 countries ➢ Results shared and analyzed during the 6th Annual Meeting

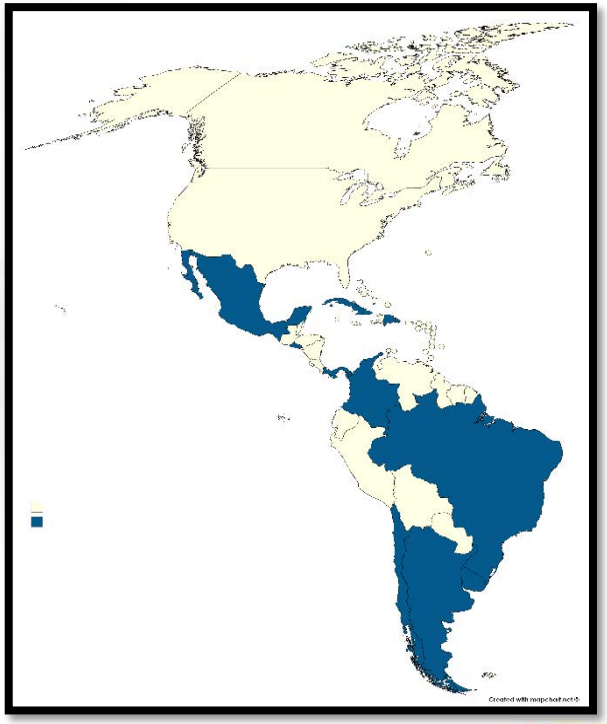
Mirror Working Group on the NCAR Exchange Program: REDMA

REDMA Web System

- ✓ Allows the implementation of the REDMA Program in an effective, safe, and confidential manner
- ✓ Only accessible to the members of the REDMA Program
- ✓ Access to the system is done through a single contact designated by each Regulatory Authority
- ✓ Future integration with PRAIS

REDMA Web System – Pilot

- **Objective:** Test the REDMA Web System to show the extent to which its functions operate according to the specifications and requirements for the exchange of adverse events reports



- February – June 2017
- Participants: Argentina, Brazil, Chile, Colombia, Cuba, Mexico, El Salvador, Panama, Dominican Republic and Uruguay
- Final report presented by CECMED (Cuba) in July 2017
- Exchange of 12 reports (9 confidential)

Capacity Building

- E-learning programs:

- Medical device regulation: developed by CECMED
- 38 participants from 9 NRA in the first edition

- Technovigilance: developed by INVIMA
- 15 participants from 6 NRA in the first edition

PANDRH Project

- Strengthening of Regulatory Capacity on Medical Devices in the Region of the Americas
  - ✓ Proposed by: CECMED – Cuba and INVIMA - Colombia with the support of the Pan American Health Organization (PAHO) and the Regional Working Group on Regulation of Medical Devices.
  - ✓ Approved on the PANDRH Steering Committee Meeting held on December 15th, 2016.

It consists of the following activities:

- ✓ Mapping of the Regulation of Medical Devices in the Americas Region
- ✓ Virtual Training Courses

PANDRH
Pan American Network for Drug Regulatory Harmonization
Pan American Health Organization
World Health Organization
Americas

New opportunities for capacity building

- Virtual Training Courses:
  - ✓ General overview of Regulation of Medical Devices — CECMED
    - Hosted in CECMED Virtual Classroom
    - Second edition to begin on March 2018
    - Available in Spanish

  - ✓ Technovigilance
    - Hosted by INVIMA and the National University of Colombia within the INVIMA Aula Virtual platform.
    - August – October 2017
    - Available in Spanish; English version is under development
    - 75 participants from 16 countries

Update of the Regional Mapping

- Mapping of the Regulation of Medical Devices in the Americas Region

Objective:

- ✓ To identify and strengthen the Regulatory capacities of Medical Devices through the "Mapping of the Regulation of Medical Devices in the Americas Region" to gradually expand the work, learning and perspectives of the Regional Working Group on Regulation of Medical Devices to the countries of the Region.

Activities:

- ✓ Update of basic indicators for the countries of the Regional WG
- ✓ Extend the mapping for the countries in the Region of the Americas

Update of the Regional Mapping

- Mapping of the Regulation of Medical Devices in the Americas Region
  - Mapping tool
    - ✓ Sent to the NRA members of the PANDRH Network to fill in as a self-assessment exercise
    - ✓ Structured in ***11 main categories***.
    - ✓ Includes **47 questions**.

Medical Devices Observatory

- Basic Indicators and results will be included on the Medical Devices Observatory within PRAIS