PAHO Update

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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.
Regional Meetings


✓ 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

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| 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
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
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.

Modules:

1. Human Resources
2. Good Regulatory Practices
3. National Regulatory System
4. Import controls
5. Marketing Authorization
6. Licensing
7. Post-marketing Surveillance
8. Regulatory inspections
9. Testing laboratories
10. Clinical Trials
11. IVDs
Medical Devices Observatory

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