PAHO Update

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IMDRF Meeting
Moscow, March 2019
REGIONAL WORKING GROUP ON MEDICAL DEVICE REGULATION

ESTABLISHED: July, 2012 with 12 countries; currently with 23.

OBJECTIVE: Strengthen regulatory capacity and promote regulatory convergence for medical devices in the Region of the Americas.

Argentina  Belize  Bolivia  Brazil  Canada  Chile

Colombia  Costa Rica  Cuba  Dominican Republic  Ecuador  El Salvador

Guatemala  Honduras  Jamaica  Mexico  Nicaragua  Panama

Paraguay  Peru  Trinidad & Tobago  Uruguay  Venezuela
### VIII REGIONAL MEETING
**22 – 23 OCTOBER 2018 - EL SALVADOR**

**22 October**
Regulators session

- Advances and challenges, at national level, on Medical Device Regulation
- Collaboration with IMDRF
- International experiences (Spain and Portugal)
- Capacity building activities
- Update on the Mirror Groups & Technical Groups
- Definition of the 2019 Work Plan

**23 October**
Stakeholders forum

- Medical Device Cyber security
- Standards
- Postmarketing Surveillance for Medical Devices in the US
- Regulatory framework for medical devices in Europe

- Hosted by DNM (NRA of El Salvador)
- Regulators session: 32 participants representing 24 countries
- Stakeholders forum: 90 participants
- 2nd Regional Meeting in conjunction with the PANDRH meeting
PAHO/WHO

COLLABORATION WITH IMDRF

- REDMA Program on the exchange of post market safety information on medical devices was launched following a mirror group of the IMDRF working group on NCAR system
- Creation of two new mirror working groups
- Participation in the IMDRF Working Groups of Medical Device Clinical Evaluation and Personalized Medical Devices (Regional Working Group represented by ANMAT, Argentina)
- Stakeholder forum in the Regional meetings
Two new Mirror Working Groups were created in the last Regional Meeting (October 2018)

- **NCAR Exchange Program: REDMA Program**
  - **COORDINATOR:** CECMED, CUBA

- **Software as a Medical Device**
  - **COFEPRIS, MÉXICO**

- **Personalized Medical Devices**
  - **ANMAT, ARGENTINA**

- **Adverse Event terminology**
  - **MINISTRY OF HEALTH, URUGUAY**
PAHO/WHO

REDMA PROGRAM

PILOT
10 PARTICIPANT COUNTRIES (ARG, BRA, CHI, COL, CUB, MEX, ELS, PAN, DOR, URU); 12 REPORTS WERE EXCHANGED THROUGH A SECURE SYSTEM DEVELOPED BY CECMED

DOCUMENTS
UPDATE OF THE PROGRAM’S OPERATIONAL AND PROCEDURAL DOCUMENTS BASED ON IMDRF DOCUMENTS.

TRAINING
ONLINE & FACE-TO-FACE

IMPLEMENTATION
LAUNCHED ON 14 MARCH 2019

SECRETARIAT
CECMED (Cuba), INVIMA (Colombia) and ANVISA (Brazil)
○ Secure exchange of reports on medical devices’ adverse events.

○ Fully integrated within the Regional Platform on Access and Innovation for Health Technologies (PRAIS).

○ Access only allowed to the NRA members of the REDMA Program.

○ Access to the web platform is done through a single contact designated by each NRA.
POST-MARKETING SURVEILLANCE (e-learning)
- Collaboration INVIMA-PAHO
- The Spanish version of the course had two editions, with 90 participants
- First edition in English for the Caribbean countries
- 7 Modules were translated into English: Technovigilance; London Protocol; Failure Mode and Effects Analysis; patient safety and clinical risk management; Reuse and reprocessing of medical devices; Signal generation; Intense surveillance and sentinel network.
- Starting date: 13 May 2019

HEALTHCARE TECHNOLOGY MANAGEMENT WORKSHOP
- In collaboration with the University of Vermont
- 27-29 March 2019
- 20 participants from the Caribbean countries

MEDICAL DEVICE REGULATION (e-learning)
- Developed by CECMED
- Course had two editions, for a total of 159 participants
- English version will be offered in 2020
Part of the first project on Medical Device Regulation at PANDRH; coordinated by INVIMA and CECMED with PAHO as the Secretariat.

Basic indicators tool:
- Sent to the NRA members of the PANDRH Network.
- Structured in 11 main categories.
- Includes 47 questions.
- Self-assessment from 22 countries.
THANK YOU!