PAHO Update

Pan American Health Organization

World Health Organization

REGIONAL OFFICE FOR THE Americas

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IMDRF Meeting

Shanghai, China

21 March 2018

Regional Working Group on Medical Device Regulation

- **Established:** July, 2012 with 12 member countries; currently with 20
- **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

- 7 Regional Meetings: Cuba (2012), Argentina (2013), USA (2014), Colombia (2015), Brazil (2016), Mexico (2016), Canada (2017)

- VII Regional Meeting: 21-22 September 2017 - Ottawa (hosted by Health Canada)
  - 3rd Regional meeting in conjunction with the IMDRF meeting (other ones in US and Brazil)
  - 21 September: open session
  - 22 September: regulators only
  - 26 representatives from 18 countries participated 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 Management Committee Meeting

- VIII Regional Meeting will be on 22-23 October, in El Salvador, in conjunction with the PANDRH (Pan American Network for Drug Regulatory Harmonization) Conference

Mirror Working Group for the NCAR Exchange Program: REDMA

- Operation and procedures documents of the REDMA Program, based on IMDRF
- On-line and f2f training
- Secretariat: CECMED (Cuba), INVIMA (Colombia) and ANVISA (Brazil)
- Software developed by CECMED (WHO Collaborating Center) for the secure exchange of adverse events reports (REDMA Web System)
- Pilot exercise performed with the participation of 10 countries (Argentina, Brazil, Chile, Colombia, Cuba, Mexico, El Salvador, Panama, Dominican Republic and Uruguay); completed in October 2017, with the exchange of 12 reports (9 confidential)
- Full implementation in 2018: next meeting in Havana, Cuba, 26 April

REDMA Program

REDMA Web System

- ✓ Allows the secure exchange of the adverse events reports
- ✓ Only accessible to the members of the REDMA Program
- ✓ Access to the system is done through a single contact designated by each Regulatory Authority
- ✓ Integration with PRAIS (Regional Platform on Access and Innovation for Health Technologies) under development

Capacity Building

- E-learning programs:

❑ Medical device regulation: developed by CECMED (Cuba)

- 1st edition: 38 participants from 9 countries
- 2nd edition: 121 participants from 16 countries

(7 January – 3 March)

❑ Post-marketing Surveillance: developed by INVIMA (Colombia)

- 1st edition: 15 participants from 6 countries
- 2nd edition: 75 participants from 15 countries

(9 August – 31 October)

- All modules translated into English; launch of the English version planned for late this year

- Training hosted by INVIMA in December 2017 with representatives from 10 NRA

Update of the Regional Mapping (1)

- Original mapping was performed in 2014-2015; the results were published in the PAHO Journal in 2016
- First version had results from 15 NRA
- The new mapping exercise is part of the first project on medical device regulation at PANDRH, proposed and coordinated by INVIMA and CECMED, with PAHO as the Secretariat
- The final results will be available at the Regional Platform on Access and Innovation for Health Technologies (PRAIS)

Update of the Regional Mapping (2)

- Mapping of the Regulation of Medical Devices in the Americas Region
  - Mapping tool
    - ✓ Sent to the NRA members of the PANDRH Network
    - ✓ Structured in ***11 main categories***.
    - ✓ Includes **47 questions**.
    - ✓ Feedback received from 20 countries in the first phase

Medical Devices Observatory

- Basic Indicators will be available in the Medical Devices Observatory within PRAIS