IMDRF International Medical Device Regulators Forum

PAHO Update

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IMDRF Meeting

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Regional Working Group on Medical Device Regulation

24 countries are currently members

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

Activities of the Regional Working Group

Regional Meetings

- Annual Face to Face Meetings
  - Open Session with stakeholders
- Virtual Meetings

Training

- Annual virtual courses in collaboration with CECMED and INVIMA
- Face to face workshops on defined priority topics

Collaboration with IMDRF

- Regional Meetings in conjunction with the IMDRF Meetings
- Participation in the Working Groups
- Mirror Working Groups
- Translation of technical documents

Technical Groups

- Reuse and reprocessing of Medical Devices
- National Implant Registry

Medical Device Indicators

- Development of Basic Indicators
- Advanced Indicators draft
- Participation in the Global Benchmarking Tool + Medical Devices

Community of Practices

- Regulation of Medical Devices
- REDMA Program

Training activities

Virtual Module on Post-market Surveillance

Developed by	November – December	
INVIMA	**2020**	**Spanish** Edition

195 Participants enrolled

90% retention

175 participants completed the course

16

Benefited countries

Argentina, Belize, Bolivia, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru

Main **Topics**

- Introduction to Medical Devices
- Technovigilance international overview
- Colombian Technovigilance
- Strenghtening technovigilance in the context of the COVID-19

Meeting of the Regional Working Group on Medical Devices Regulation

- Held on 13 October 2020
- 30 participants from 15 countries

TOPICS

- **Global Benchmarking Tool + Medical Devices**
- **Update on the collaboration with IMDRF**
- **Mirror Working Groups**
- **Program on exchange of reports on adverse events of Medical Devices - REDMA Program**
- **Regulation of Personal Protective Equipment**

Meeting of the Program on exchange of reports on adverse events of Medical Devices - REDMA Program

- Held on 11 August 2020.
- Participation of 55 representatives of 17 Regulatory Authorities from: ARG, BOL, BRA, CHL, COL, CRI, CUB, DOR, ECU, GTM, MEX, NIC, PRY, SLV, URY, USA, VEN.

TOPICS

- **Results of the training activity on the REDMA Program**
- **Adverse events related to ventilators in the context of COVID-19**
- **Discussion of other COVID-19 related adverse events**
- **Discussion on adverse events' reports included on the REDMA Web System**

Medical Devices Indicators

WHO Global Benchmarking Tool + Medical Devices

WHO Working Group for the integration of indicators on Medical Devices and In Vitro Diagnostics into the GBT

PAHO participates in the activities of the Working Group coordinated by WHO, with the following NRA from the Region of the Americas:

- ANMAT, Argentina
- ANVISA, Brazil
- CECMED, Cuba
- COFEPRIS, Mexico
- FDA, USA
- Health Canada, Canada
- INVIMA, Colombia

PAHO advanced indicators tool was incorporated into the WHO GBT+ Medical Devices.

Work related to Medical Devices in response to COVID-19

- **Dissemination of information** with the *Regional Working Group* (Alerts, regulatory updates, publication of technical guidelines)
  - Weekly monitoring of COVID-19 related alerts and updates on post-market surveillance in the following agencies: AEMPS – Spain; ANMAT – Argentina; ANVISA – Brazil; CECMED – Cuba; COFEPRIS – Mexico; DIGEMID – Peru; FDA - USA; Health Canada – Canada; HSA – Singapore; INFARMED – Portugal; INVIMA – Colombia; TGA - Australia.
- Coordination of **webinars** and **virtual meetings** to share experiences and promote cooperation among countries of the Region
  - Meeting on *Regulation of Personal Protective Equipment,* 1 December 2020.
    - 43 participants from 13 countries.
    - Main topics: Challenges on PPE Regulation in the Americas, Panel on Experiences in the Regulation of PPE in the countries of the Americas with the participation of ANMAT – Argentina, CECMED – Cuba, Dirección Nacional de Medicamentos - El Salvador.

Work related to Medical Devices in response to COVID-19

- **Quality assurance** of up to 150 Medical Devices, including Biomedical Equipment, In Vitro Diagnostics and Personal Protective Equipment procured through PAHO.
- **Technical support** to Member States in the evaluation of Medical Devices as part of local purchases or donations.
- **Training** sessions on quality assurance and operation of Biomedical Equipment procured through PAHO benefiting up to 350 participants.
  - ❑ 3 training sessions on quality assurance of Biomedical Equipment
  - ❑ 2 training sessions on the operation of oxygen concentrators

Thank you!!