PAHO Update

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IMDRF Meeting
13 September 2022
Regional Working Group on Medical Devices Regulation

Established in 2012 with the objective of strengthening the regulatory capacity of medical devices in the Americas - **25 NRA** are currently members.

<table>
<thead>
<tr>
<th>Argentina</th>
<th>Belize</th>
<th>Bolivia</th>
<th>Brazil</th>
<th>Canada</th>
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<tbody>
<tr>
<td>Chile</td>
<td>Colombia</td>
<td>Costa Rica</td>
<td>Cuba</td>
<td>Dominican Republic</td>
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<td>Ecuador</td>
<td>El Salvador</td>
<td>Guatemala</td>
<td>Guyana</td>
<td>Honduras</td>
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<td>Jamaica</td>
<td>Mexico</td>
<td>Nicaragua</td>
<td>Panama</td>
<td>Paraguay</td>
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<tr>
<td>Peru</td>
<td>Trinidad &amp; Tobago</td>
<td>Uruguay</td>
<td>USA</td>
<td>Venezuela</td>
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Activities of the Regional Working Group

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

- **Regional Meetings**

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

- **Collaboration with IMDRF**

- **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
X Regional Meeting of Regulatory Authorities for the Strengthening of the Regulatory Capacity of Medical Devices in the Americas

1 - 3 June 2022

In collaboration with the Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector

TOPICS

- Regional Working Group on Medical Devices Regulation
- Good Regulatory Practices for Medical Devices
- The Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector and its work in support of advances in the Region
- Good Reliance Practices in Emergency Use Authorizations for Medical Devices

Session recordings and material can be consulted at: https://www.paho.org/es/temas/dispositivos-medicos

VIRTUAL MODE

<table>
<thead>
<tr>
<th>Open Session</th>
<th>Closed Session</th>
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<tbody>
<tr>
<td>Regional Work Group</td>
<td>Regulators</td>
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<tr>
<td>1-2 June</td>
<td>2-3 June</td>
</tr>
<tr>
<td>250 participants</td>
<td>100 participants</td>
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TOPICS

- Capacity-building activities
- REDMA Program
- Regulation of In Vitro Diagnostics
- HEARTS Initiative
- PAHO/WHO WHO Collaborating Centre for the Regulation of Health Technologies
- Medical Device Nomenclature
- Global Benchmarking Tool + Medical Devices
- WHO Collaborative Registration Procedure
- Global Model Regulatory Framework
- IMDRF Activities
- Assistive Products
X Meeting of Regulatory Authorities for the Strengthening of the Regulatory Capacity of Medical Devices in the Americas

3 June 2022 – Closed session
Policy to Strengthen Regulatory Systems for Medicines and other Health Technologies

To promote efficient regulatory systems with maturity level 3 or higher in all Member States, tailored to the needs of their health systems and ensuring the quality, safety, and efficacy of health technologies in accordance with WHO recommendations.

In addition, where established by national policies and where the context permits, regulatory systems should encourage the production of health technologies that promote health and well being, as well as economic and social development.

Next Steps:
- Consultation sessions with MS were held in February-March;
- PAHO internal review process;
- Edition and publication in all official languages;
- 20-24 June 2022, the Executive Committee was invited to review the Policy, adopt the proposed Resolution, and recommend its adoption at the 30th Pan American Sanitary Conference, to be held on 26-30 September 2022.
Capacity building activities in 2021/2022

Virtual module on post-market surveillance

In collaboration with INVIMA

2021 Edition

Spanish

125 participants

14 beneficiary countries
Bolivia, Chile, Costa Rica, Cuba, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Paraguay, Peru, Uruguay, Venezuela

Main TOPICS

• Introduction to Medical Devices and international overview of technovigilance
• Progress, challenges and projection of the Colombian technovigilance program
• Steps to implement a technovigilance program in Colombia
• Strengthening technovigilance in the context of COVID-19
Collaboration with IMDRF

12 documents translated into Spanish (1)

https://iris.paho.org/handle/10665.2/56058

https://iris.paho.org/handle/10665.2/56051

https://iris.paho.org/handle/10665.2/56047

https://iris.paho.org/handle/10665.2/56043

https://iris.paho.org/handle/10665.2/56042

https://iris.paho.org/handle/10665.2/56041
Collaboration with IMDRF

12 documents translated into Spanish (2)

https://iris.paho.org/handle/10665.2/56258

https://iris.paho.org/handle/10665.2/56257

https://iris.paho.org/handle/10665.2/56256

https://iris.paho.org/handle/10665.2/56255

https://iris.paho.org/handle/10665.2/56254

https://iris.paho.org/handle/10665.2/56253
Collaboration with IMDRF

3 documents translated into Portuguese
Collaboration with IMDRF

6 new translations (into Spanish) under development:

1. Clinical Evaluation
2. Tools for Assessing the Usability of Registries in Support of Regulatory Decision-Making
3. UDI Guidance. Unique Device Identification (UDI) of Medical Devices
4. Principles of International System of Registries Linked to Other Data Sources and Tools
5. Unique Device Identification system (UDI system). Application Guide
6. Post-Market Clinical Follow-Up Studies
Program on exchange of reports on adverse events of Medical Devices - REDMA Program

<table>
<thead>
<tr>
<th>Associate Members</th>
<th>Full Members</th>
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<tr>
<td>BOL</td>
<td>ECU</td>
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37 Reports
24 Confidential - 13 Public

- 86% of the reports are confidential.
- Health institutions reported 50% of the events, manufacturers 37%, and users 13%.
- Risk level of the reported devices: 38% Low-Moderate; 29% High; 21% Moderate-High; 12% Low.
- The most reported medical specialty was cardiovascular health with 21%.
Project to strengthen testing capacity for PPE quality control laboratories

Lessons learned:
- The regional production capacity for health technologies is insufficient
- Access to medical products depends on supply chains that are vulnerable
- The shortage of PPE was one of the first consequences
- The importance of improving the analytical capacity of laboratories was highlighted

Objective
Strengthen the analytical capacity of NRA Quality Control Laboratories (QCL) in the Region

How
Purchasing laboratory equipment for quality control of PPE

Scope
- Respirators
- Medical masks
- Gloves

specific objective: support two QCLs to work as subregional hubs (Central and South America)

Milestones
- 31 pieces of equipment were procured for the NRA QCL in El Salvador and Colombia
- Total amount invested: USD$1.1 million
Quality assurance of medical devices in the context of the COVID-19 response

Eligibility criteria
- Regulatory compliance (IMDRF Members, WHO SRAs for IVDs, manufacturing country)
- Documentation to demonstrate compliance with technical requirements

Manufacturer
- Manufacturing license issued in the country of origin
- Certified Quality Management System
- Application of risk management to medical devices, if applicable

Product safety and performance
- Evaluation process based on the technical specifications and applicable international standards (recommended to each medical device)
- Evidence to demonstrate compliance with applicable standards

Labelling
- Instructions for use, service manual, user manual, technical specifications.
- Compliance with the principles of the document IMDRF/GRRP WG/N52 FINAL:2019
Technical support related to Medical Devices

<table>
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<tr>
<th>Quality assurance assessment</th>
<th>Technical support related to local procurement of MD</th>
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<tbody>
<tr>
<td>149 medical devices</td>
<td>444 medical devices</td>
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<td>19 benefited countries</td>
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Information from Jan-Aug, 2022
Regulation of Assistive Products (APs) in the Americas

### Main components
- Assessment of the regulatory situation of APs in the Region
- Development of a virtual course
- Development of a guidance tool on regulation

### Activities
- **Indicators on APs**
  - Pilot to be implemented later this year
- **Introductory course on AT**
  - 324 certified professionals, 26 countries
  - Topic on strengthening regulation of APs is included
- **Under development**
Thank you!