Regulation of Medical Devices in the Americas

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Third WHO Global Forum on Medical Devices

Geneva, 10-12 May 2017
Regional Working Group on Medical Devices

- **Established:** July, 2012 with 12 countries; currently with 16
- **Objective:** Strengthen the regulatory capacity for medical devices in the Region of the Americas.

- Argentina
- Brazil
- Canada
- Chile
- Costa Rica
- Cuba
- Colombia
- Dominican Republic
- Ecuador
- El Salvador
- Honduras
- Mexico
- Panama
- Paraguay
- Peru
- Uruguay
Regional meetings (1)


✓ Last Regional Meeting: October, 2016, Ciudad de Mexico (45 participants from 17 countries; 2 CARICOM members: Belize, Trinidad and Tobago)

  ➢ In conjunction with the PANDRH meeting
  ➢ Update on IMDRF activities and synergies with the Regional WG
  ➢ Update on the Report Exchange Program on Medical Devices between NRAs in the Region of the Americas – REDMA Program
  ➢ Update on the Mirror Group: “Software as a Medical Device”
  ➢ Update on the Technical Group: “Reprocessing of Medical Devices”
  ➢ Capacity building activities in the Regional WG
  ➢ Advanced indicators
  ➢ Priorities of PANDRH and synergies with the Regional WG
  ➢ Definition of the 2016 – 2017 Work Plan
Regional meetings (2)

- For the very first time, there was an Open Session where the Regional WG interacted with the industry and other interested parties on the following topics:
  - Technovigilance
  - Software as MD
  - Reprocessing & Reuse of MD
- 120 participants
- Participants concluded that the dialog between industry and Regulatory Authorities is key to achieving a fair regulatory process
- The Regional WG will seek to open discussion spaces in the future
Regional Mapping on the Regulation of Medical Devices

RATIONALE: During the 1st Regional Meeting (2012), a mapping activity on the regulation of Medical Devices in the Region was appointed as a priority. (Argentina, Brazil, Canada, Chile, Colombia, Costa Rica, Cuba, Honduras, Mexico, Panama, Peru, Uruguay, OPS, OMS)

OBJECTIVE: To assess the current situation of the Regulation of Medical Devices in the Region.

SURVEY: It was developed in collaboration with the Ministry of Health of Uruguay.
   - Structured in **6 main categories**.
   - Consists on **45 questions**.
<table>
<thead>
<tr>
<th>Indicadores</th>
<th>% of achievement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1100- Is there an institution responsible for regulating medical devices?</td>
<td>93</td>
</tr>
<tr>
<td>1101- Are there regulations establishing the attributions of the institution responsible for the regulation of medical devices?</td>
<td>93</td>
</tr>
<tr>
<td>1102- Is there a process for the registration of Medical Devices?</td>
<td>93</td>
</tr>
<tr>
<td>1103- Are Medical Devices being categorized by risk for registration purposes?</td>
<td>86</td>
</tr>
<tr>
<td>1105- Are there regulations establishing the attributions of the institution responsible for the post-marketing vigilance of medical devices?</td>
<td>79</td>
</tr>
<tr>
<td>1104- Is there an official Nomenclature System for Medical Devices?</td>
<td>71</td>
</tr>
<tr>
<td>1107- Are there regulations related to the donations of medical devices?</td>
<td>64</td>
</tr>
<tr>
<td>1108 - Are there working alliances with other countries to strengthen the regulatory capacity for medical devices?</td>
<td>43</td>
</tr>
<tr>
<td>1109 - Are there specific policies to regulate the incorporation of new technologies and the acquisition of strategic products?</td>
<td>36</td>
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</tbody>
</table>
# Results (2)

<table>
<thead>
<tr>
<th>Country</th>
<th>Critical indicators achieved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Argentina</td>
<td>6</td>
</tr>
<tr>
<td>Brasil</td>
<td>6</td>
</tr>
<tr>
<td>Canada</td>
<td>6</td>
</tr>
<tr>
<td>Cuba</td>
<td>6</td>
</tr>
<tr>
<td>Colombia</td>
<td>6</td>
</tr>
<tr>
<td>Mexico</td>
<td>6</td>
</tr>
<tr>
<td>Peru</td>
<td>6</td>
</tr>
<tr>
<td>Uruguay</td>
<td>6</td>
</tr>
<tr>
<td>Costa Rica</td>
<td>5</td>
</tr>
<tr>
<td>Chile</td>
<td>5</td>
</tr>
<tr>
<td>Panama</td>
<td>5</td>
</tr>
<tr>
<td>Ecuador</td>
<td>4</td>
</tr>
<tr>
<td>Honduras</td>
<td>4</td>
</tr>
<tr>
<td>Paraguay</td>
<td>2</td>
</tr>
<tr>
<td>Dominican Republic</td>
<td>1</td>
</tr>
</tbody>
</table>
OBJECTIVE: To assess the level of implementation of the Medical Devices Regulation in the Region.

TOOL: Adapted from PAHO/WHO National Regulatory Authority assessment tool for medicines, in collaboration with CECMED as WHO/PAHO Collaborating Centre for the Regulation of Health Technologies.

- It is structured in 7 main categories
- It consists of 104 indicators (3rd version)
Regional Mapping on the Regulation of Medical Devices

Literary review and first draft of advanced indicators

The first draft of the Assessment Tool was sent to 14 countries for feedback

The first draft of the Assessment Tool was discussed during the III Regional Meeting

The second draft of the Assessment Tool was built based on comments received via e-mail and during the III Regional meeting

A pilot study was performed with 5 voluntary countries: Colombia, Cuba, Ecuador, Mexico and Panama

The pilot results were presented, analyzed and discussed during the IV Regional meeting

CECMED and COFEPRIS represented the Regional Working Group during a meeting with WHO - Geneva towards a WHO/PAHO Assessment Tool

The third draft of the Assessment Tool was built based on comments received during the IV Regional meeting

- Argentina
- Brazil
- Canada
- Chile
- Colombia
- Cuba
- Dominican Republic
- Ecuador
- Honduras
- Mexico
- Panama
- Peru
- Uruguay
- EUA
- OMS
Pilot Assessment

- Performed with 5 voluntary countries: Colombia (INVIMA), Cuba (CECMED), Ecuador (ARCSA), Mexico (COFEPRIS) and Panama (Ministry of Health).
Module 4. Post-marketing surveillance

<table>
<thead>
<tr>
<th>Module 4 - Critical</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1</td>
</tr>
<tr>
<td>NA</td>
</tr>
<tr>
<td>NI</td>
</tr>
<tr>
<td>OI</td>
</tr>
<tr>
<td>PI</td>
</tr>
<tr>
<td>I</td>
</tr>
</tbody>
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NA – Not Applicable  PI – Partially Implemented
NI – Not Implemented  I - Implemented
OI – Ongoing Implementation
# Update on the Working Groups

<table>
<thead>
<tr>
<th>Mirror Working Groups</th>
<th>Topic</th>
<th>Secretariat</th>
<th>New activities</th>
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|                       | REDMA Program | Cuba (CECMED) Brazil (ANVISA) Colombia (INVIMA) | ➢ 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  
➤ Feedback from 8 countries  
➤ Results shared and analyzed during the 6th Annual Meeting |
| Technical Group | Reuse and reprocessing of medical devices | INVIMA (Colombia) ANAMED (Chile) ANVISA (Brazil) COFEPRIS (Mexico) DIGEMID (Peru) | ➢ Mapping activity on the Regulation of the Reprocessing and Reuse of Medical Devices  
➤ Feedback from 14 countries  
➤ Final report concluded |
Mirror Working Group on the NCAR Exchange Program: REDMA Program

REDMA Web System

- Allows the implementation of the REDMA Program in an effective, safe, and confidential manner according to the requirements that the exchange of adverse events demands

- Only accessible to the members of the REDMA Program

- Access to the system will be done through a single contact defined by each Regulatory Authority
**REDMA Web System – Pilot Activity**

- **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.

- **Convocation date:** February 13th, 2017

- Invitation extended to the countries that participated in the Technical Meeting (2016): Argentina, Brazil, Chile, Colombia, Cuba, Mexico, El Salvador, Panama, Dominican Republic and Uruguay.

  ✓ All of the countries that were invited have confirmed their participation in the pilot activity.
Virtual Training

- Virtual Course on Technical Surveillance and Adverse Events
  - Hosted by INVIMA and the National University of Colombia within the Platform INVIMA Aula Virtual.
  - Available in Spanish

- Virtual course on Regulation of Medical Devices
  - Hosted in CECMED Virtual Classroom
  - Available in Spanish

- The English version of the virtual courses is under development

- In collaboration with PANDRH, the Virtual Courses will be accessible to more professionals
Next steps

- 7th Regional Meeting of the Regulatory Authorities for the Strengthening of the Regulatory Capacity of Medical Devices in the Region of the Americas – to be hosted by Health Canada, Canada (September, 2017)
  - In conjunction with the IMDRF Meeting

- Complete the pilot activity of the REDMA Web System and integrate it within PRAIS

- Launch the English version of the courses

- Update the basic indicators, including the countries that did not participate in the first phase and incorporating the information into PRAIS

- Strengthen the advanced indicators assessment tool, seeking convergence with the WHO assessment tool

- Dissemination of the WHO Global Model Regulatory Framework for Medical Devices