Strengthening Medical Device Regulatory Capacity in the Americas: working towards regulatory convergence

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Global Harmonization Summit
Washington-DC, September 2014
Brief history, important achievements

1999
- 7th GHTF meeting, USA
- First meeting of PACME (Pan American Cooperation on Medical Equipment), USA
- Regional consultation meeting on Medical Device Regulation
- ListServ MED-DEVICES created

2000
- 8th GHTF meeting, Canada
- 2nd PACME meeting, Canada
- Resolution CD42.R.10 approved in PAHO Directive Council: Member States urged to develop and strengthen programs for the regulation of medical devices

2001
<table>
<thead>
<tr>
<th>Year</th>
<th>Events</th>
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| 2002 | 9th GHTF Conference, Singapur  
      | 3rd PACME meeting, Singapur  
      | 2nd APEC (Asia-Pacific Economic Cooperation), Singapur.  
      | PAHO/WHO: A Guide for the Development of Medical Devices Regulations (in cooperation with Health Canada)  
      | Subregional Workshop for Central American countries |
| 2003 | Subregional workshop for Andean countries  
<pre><code>  | WHO: Medical Device Regulations: Global Overview and Guiding Principles |
</code></pre>
<p>| 2004 | International meeting ISO-GHTF-WHO-PAHO |</p>
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<tr>
<th>Year</th>
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| 2006 | - 10th GHTF Conference, Germany.  
- 4th PACME meeting, Chile.  
- 3rd APEC meeting, Chile.  |
| 2007 | - Resolution WHA60.29: Health Technologies  
- 11th GHTF Conference, USA.  
- 5th PACME meeting, USA.  
- Internacional meeting on Tecnovigilance, Colombia. |
| 2008 | - 4th APEC, Malasia |
| 2009 | - 12th GHTF Conference, Canada.  
- 6th PACME meeting, Canada.  
- 5th APEC meeting, Canada.  
- International Regulatory Forum, Canada. |
2010
• 1st WHO Global Forum on Medical Devices, Thailand
• Foro Regulatorio Internacional, Canadá
• WHO Baseline country survey on medical devices.

2011
• International Regulatory Forum, Health Canada
• International Medical Device Regulators Forum (IMDRF) is conceived, meeting in Canada

2012
• Regional working group for the strengthening of medical device regulatory capacity in the Americas is conceived
• First meeting of the Working Group, Cuba
• Community of Practice of Medical Device Regulators is launched within the Regional Platform in Access and Innovation-PRAIS
• International Regulatory Forum, Canada
• IMDRF meeting, Singapore
• IMDRF meeting, Australia
• Resolution CSP28.R9: Health Technology Assessment, adopted by Member States at the Pan American Sanitary Conference
• Regulation of medical devices is considered priority number one by the members of PANDRH, and for the first time a plenary session about this topic is part of the Network meeting
2013

- 2nd WHO Global Forum, Switzerland
- II Regional Working Group meeting, Argentina.
- Workshop “Regulatory-HTA interaction”, Brazil
- International Regulatory Forum, Canada
- IMDRF meeting, France
- IMDRF meeting, Belgium

2014

- CECMED Cuba recognized as WHO/PAHO Collaborating Center for regulation of medical devices
- III Regional Working Group meeting, USA
- IMDRF meetings, USA
- International Regulatory Forum, Canada
- Resolution WHA67.20: Regulatory Systems Strengthening for Medical Products
- Resolution WHA67.23: HTA in support of Universal Health Coverage
Regional Working Group: establishing priorities

First meeting in July 2012, with 12 countries

- Argentina
- Brasil
- Canada
- Chile
- Colombia
- Costa Rica
- Cuba
- Honduras
- Mexico
- Panama
- Peru
- Uruguay

- Priorities defined in the Havana meeting:
  - Map the current regulatory situation in each country
  - Develop a way to effectively exchange information amongst agencies
  - Capacity building
  - Assessment tool for the evaluation of regulatory authorities
  - Explore interaction HTA-Regulation
First results

Presented at the 2\textsuperscript{nd} meeting in Buenos Aires (June 2013):

- Mapping template with 45 questions, applied to 14 countries
- Exchange of information: community of practice within the PRAIS
- International Regulatory Forum and proposal for a virtual course on Regulation and HTA
- Interaction Regulation-HTA: pilot project PAHO/USAID
Objective: to know the current situation of the regulation of medical devices in the Region.

First phase with 14 countries
- Argentina
- Brazil
- Canada
- Chile
- Colombia
- Costa Rica
- Cuba
- Ecuador
- Honduras
- Mexico
- Panama
- Peru
- Dominican Rep.
- Uruguay

45 questions
6 categories
- Medical Devices Regulation structure
- Legislation
- Regulation for the manufacturers of medical devices
- Organizational structure of the regulatory authorities
- Health risks communication
- Incorporation of new technologies
Proposal approved in the Cuba meeting - 2012

First results presented in Argentina and Canada 2013

Mapping

Next step: indicators
Basic indicators

1100- Is there an institution responsible for the medical devices regulation?

1101- Is there any legislation that establishes the mandate of the institution responsible for the regulation of medical devices and medical equipment?

1102- Is there a registration process established?

1103- Are the products classified according to their health risk?

1104- Is there any Official Nomenclature System of medical equipment or medical devices such as UMDNS, GMDN, or others?

1105- Are there legislations establishing the mandate of the institution responsible for the post-marketing surveillance of medical devices?

1106- Is there a legislation concerning the management of medical devices?

1107- Is there a regulation related to medical device donations?

1108- Are there regulations related to the incorporation of new health technologies into the health systems?
## Preliminary Results (1)

<table>
<thead>
<tr>
<th>Indicators</th>
<th>% of compliance</th>
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<tr>
<td>1100- Is there an institution responsible for the medical device regulation?</td>
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<td>1101- Is there any legislation that establishes the mandate of the institution responsible for the regulation of medical devices and medical equipment?</td>
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<td>1102- Is there a registration process established?</td>
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<td>1103- Are the products classified according to their health risk?</td>
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<tr>
<td>1105- Are there legislations establishing the mandate of the institution responsible for the post-marketing surveillance of medical devices?</td>
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<tr>
<td>1104- Is there any Official Nomenclature System of medical equipment or medical devices such as UMDNS, GMDN, or others?</td>
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<td>1107- Is there a regulation related to medical device donations?</td>
<td>64</td>
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<td>1108 - Are there collaborative alliances with other countries to unify efforts in the regulation of medical devices?</td>
<td>43</td>
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<td>1109 - Are there specific regulation policies related to the incorporation of new technologies in the health systems?</td>
<td>36</td>
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## Preliminary Results

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<th>Country</th>
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93% of the countries have some kind of regulation

**Preliminary Results**

*Registration*
- 64% Apply to 100% of medical devices
- 14% Apply to more than 50%
- 14% Apply to less than 50%

*Quality control*
- 21% Apply to 100% of the devices
- 28% Apply to specific cases of medical devices
- 50% Apply when there is a report
There is post-marketing surveillance regulation.

There is regulation related to pre-market and post-market quality control for medical devices.

There is regulation to classify the medical devices according to their risk.
Regulation of medical device companies

- There is regulation for licensing companies responsible for medical equipment maintenance.
- There is specific regulation for licensing import companies.
- There is regulation for licensing of medical devices manufactures.
Capacity building and collaboration

- Have conformed working groups or alliances with other regulatory institutions
- Have experienced successful trainings inside the organization
- There are permanent training programs for the staff working on medical devices regulation
Goal: To provide an effective way for the exchange of information about regulation of medical devices between regulatory authorities.
Capacity Building

• Since 2012, PAHO and Health Canada have been supporting countries from the Region to participate in the International Regulatory Forum, a one week program with activities targeted to medical device regulators.

• Courses on Health Technology Assessment and on Medical Device Management will be launched in September 2014 in the PAHO Virtual Campus; a course on Regulation is planned to be launched in 2015.
Project “Regulatory-HTA interactions”

• Considering the existing gap on medical devices regulation and the growing interest for the interaction HTA-Regulation, a pilot project was developed by PAHO (funded by USAID)

• The project had the following products:
  - Review of the literature and current initiatives on the HTA-Regulatory interactions
  - Case studies in four countries: Colombia, Mexico, Uruguay and Argentina
  - Design of a virtual course on HTA and Regulation
  - Workshop in September 2013 (hosted by Anvisa and MoH Brasil) to present the results and to discuss an agenda for collaboration between the working group of regulatory authorities and RedETSA
Agenda 2014/2015

- III Regional meeting has been held in conjunction with IMDRF meeting, in Washington, and one of the goals was to explore synergies and opportunities for collaboration between the Regional group and IMDRF
  - Two main proposals have emerged as a result of the discussion:
    - The request to IMDRF Management Committee the status of affiliate organization for PAHO
    - To create mirror regional groups
  - To support the participation of countries from the Region in the International Regulatory Forum
  - To implement the Collaborating Center (CECMED) work plan
  - To develop advance indicators in order to have a Regional Profile on Medical Device Regulation
  - To launch the course on Regulation of Medical Devices in the PAHO Virtual Campus