Regulation of Medical Devices:

a Regional approach

Pan American Health Organization

World Health Organization

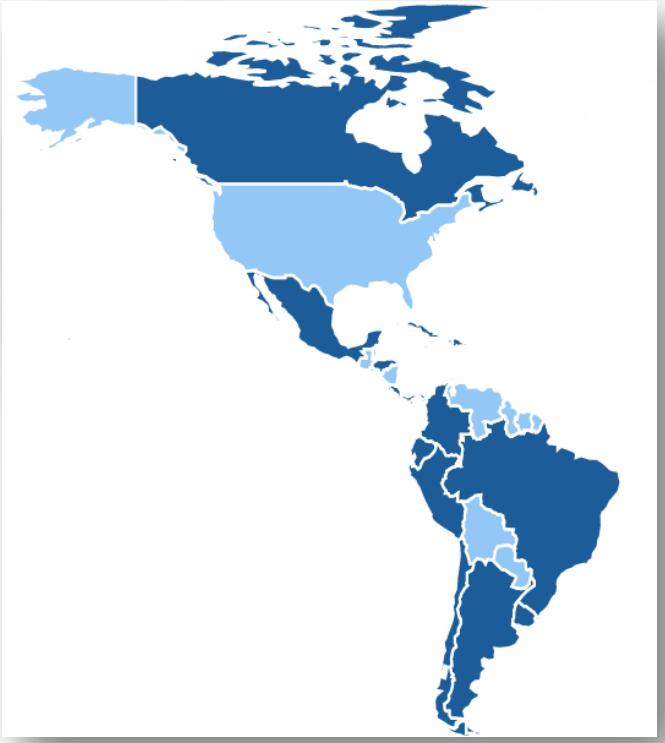
REGIONAL OFFICE FOR THE Americas

IMDRF Meeting

Working Group on Medical Devices

- Established in July, 2012 with 12 countries; currently with 14
- **OBJECTIVE:** To strengthen the regulatory capacity for medical devices in the Region of the Americas.

Argentina	Brazil	Canada	Chile
Costa Rica	Cuba	Colombia	Dominican Republic
Ecuador	Honduras	Mexico	Panama
	Peru	Uruguay	



Regional meetings (1)

- **1st Regional Meeting of the Regulatory Authorities for the Strengthening of the Regulatory Capacity of Medical Devices in the Americas. July 2012 – La Habana, Cuba** (Argentina, Brazil, Canada, Chile, Colombia, Costa Rica, Cuba, Honduras, Mexico, Panama, Peru, Uruguay)
  - ✓ Priorities were established for the Working Group
  - ✓ Mapping proposal approved on the regulation of Medical Devices
  - ✓ Effective exchange of information through a Community of Practices

- **2nd Regional Meeting of the Regulatory Authorities for the Strengthening of the Regulatory Capacity of Medical Devices in the Americas Region. July 2013 – Buenos Aires, Argentina** (Argentina, Brazil, Canada, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, Honduras, Mexico, Panama, Peru, Uruguay)
  - ✓ Preliminary results of the Regional mapping presented
  - ✓ Decision to develop a second phase of the mapping, building advanced indicators aimed to assess the implementation of the regulation

Regional meetings (2)

- **Workshop on the Interaction between Regulation and Health Technology Assessment (HTA). September, 2013 - Brasilia, Brazil.**
  - ✓ Discussions on the opportunities for interaction between HTA bodies/Payers/Regulators.
  - ✓ Four case studies focused on Medical Devices in Argentina, Colombia, México and Uruguay.

- **3rd Regional Meeting of the Regulatory Authorities for the Strengthening of the Regulatory Capacity of Medical Devices in the Region of the Americas. September, 2014 – Washington D.C., USA** (Argentina, Brazil, Canada, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, Honduras, Mexico, Panama, Peru, Uruguay, USA)
  - ✓ Training opportunities at the Regional level (INVIMA, CECMED).
  - ✓ Advanced indicators proposal approved by the Working Group.
  - ✓ Regional meeting in conjunction with IMDRF meeting.
  - ✓ Designation of PAHO as an IMDRF Affiliate Organization.

- **4th Regional Meeting. October, 2015 - Bogota, Colombia** (18 countries were invited)

PAHO as an IMDRF Affiliate Organization

- PAHO became an IMDRF Affiliate Organization in September 2014.
- This recognition facilitates the interaction between IMDRF and the countries from the Americas that are not members of IMDRF.
- The first concrete activity as part of this new interaction is the creation of a working group that will mirror the IMDRF working groups on a selected topic. Among the topics that are under discussion by IMDRF members, the Regional Group decided to create one working group on the:
  - NCAR Exchange Program

Mirror working group on the NCAR exchange program of the America's Region

- An initial proposal of the NCAR mirror group was elaborated by the WHO/PAHO Collaborating Centre for the Regulation of Health Technologies (CECMED).
- The background document *"Criterios y Formulario para el Intercambio de Reportes en Dispositivos Médicos entre las Autoridades Reguladoras Nacionales de la Región de las Américas"* was compiled by CECMED and shared with Brazil (ANVISA) and Colombia (INVIMA).
- Based on the feedback received, a second draft of the document *"Criterios y Formulario para el Intercambio de Reportes en Dispositivos Médicos entre las Autoridades Reguladoras Nacionales de la Región de las Américas"* will be compiled and shared between the Working Group (14 countries) for their input.

Advanced indicators

OBJECTIVE: To develop and validate advanced indicators in order to assess the level of implementation of the Medical Devices Regulation in the Region.

TOOL: Adapted from PAHO/WHO assessment tool, 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 ***108 indicators***

Advanced indicators (2)

Regional Mapping on the Regulation of Medical Devices

- ✓ National Regulatory Authority assessment tool for medicines (PAHO/WHO tool)

Literary review and first draft of advanced indicators

The draft was sent to 14 countries for feedback

- Argentina
- Brazil
- Canada
- Chile
- Colombia
- Costa Rica
- Cuba
- Dominican Republic
- Ecuador
- Honduras
- Mexico
- Panama
- Peru
- Uruguay

The assessment tool was discussed during the 3rd Regional Meeting on Regulation of Medical Devices

The second version of the advanced indicators was built based on comments received

A pilot study is being performed with 5 countries: Colombia, Cuba, Ecuador, Mexico and Panama

The methodology for application is under development

Advanced indicators (3)

NEXT STEPS

(1) Considering the results of the pilot study, the advanced indicators will be integrated in a WHO/PAHO assessment tool.

(2) The methodology for application will be shared with the Regional Working Group.

(3) This results will be the basis to develop the Regional Regulatory Profile.

Capacity building (1)

- **International Regulatory Forum – Health Canada**
  - ✓ Members of the Working Group have been participating since 2012.
  - ✓ Participation supported with funds from the Canada-PAHO Working Plan.
  - ✓ Opportunity for information exchange among countries.
  - ✓ Very positive feedback from the Working Group.

- **Online introductory courses (1&2) on Medical Devices were launched on PAHO's Virtual Campus for Public Health**

Capacity building (2)

Introductory Course on Medical Devices

- Introduction into patient care technology: the environment, a background review of the human body and technical principles—and a specific focus on medical devices commonly found at the bedside in intensive care units.
- Course at the PAHO Virtual Campus, in partnership with the University of Vermont.
- 53 participants (from 28 countries) chosen through a careful selection process.

MAIN TOPICS:

- Device principles
- Proper clinical application
- Patient safety
- Common device/technique problems and resolution
- Care, maintenance, and quality assurance
- Technology management

Spanish version:

-252 applications

-34 selected

-Participants from 19 countries:

Argentina, Bolivia , Brazil, Chile, Colombia, Costa Rica, Cuba, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Dominican Republic, Uruguay and Venezuela.

English version:

-47 applications

-19 selected

-Participants from 9 countries:

Anguilla, Antigua y Barbuda, Barbados, Bahamas, Belize, Dominica, Guyana, Saint Vincent & the Grenadines and Trinidad & Tobago.

Capacity building (3)

Introductory Course on Medical Devices – Part 2

- Upon completion of the course, the student will be able to solve basic common problems of the biomedical technology.
- Course at the PAHO Virtual Campus, in partnership with the University of Vermont.
- 48 participants (from 28 countries) invited upon successful completion of the Introductory course on Medical Devices.

MAIN TOPICS: Advanced Technology in Health Care, Quality Imaging, Imaging, Fluoroscopy, Computed Tomography, Nuclear Medicine, Radiation Therapy, Clinical Information Systems, Clinical Laboratory, Electro surgery, Minimally Invasive Robotic Surgery, Lasers, Physical therapy equipment, Fans, Health technology management, Health technology life cycle, Security and Risk Management, Clinical Engineering.

Spanish version:

- 29 enrolled students
- Participants from 19 countries:

Argentina, Bolivia , Brazil, Chile, Colombia, Costa Rica, Cuba, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Dominican Republic, Uruguay and Venezuela

English version:

- 19 enrolled students
- Participants from 9 countries:

Anguilla, Antigua y Barbuda, Barbados, Bahamas, Belize, Dominica, Guyana, Saint Vincent & the Grenadines and Trinidad & Tobago.

Looking to the future…

- 4th Regional Meeting on Regulation of Medical Devices, Bogota, October 2015, to be hosted by INVIMA.
  - ✓ Approve final draft of the background document on the NCAR mirror working group and implementation plan.
  - ✓ Discuss results of the pilot study of advanced indicators in 5 countries in order to reach a final document.
  - ✓ Launch the Techno-Vigilance course (INVIMA) in the Virtual Campus.
- 5th Regional Meeting on Regulation of Medical Devices, Brazil 2016 to be hosted by ANVISA, in conjunction with IMDRF Meeting.