

# Update on the Regional Working Group



Pan American  
Health  
Organization



World Health  
Organization

REGIONAL OFFICE FOR THE Americas

**Alexandre Lemgruber**

**IMDRF Meeting**

Brasilia, 8 - 10 March 2016

# Regional Working Group on Medical Devices

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

- Established in July, 2012 with 12 countries; currently with 16
- **OBJECTIVE:** To strengthen the regulatory capacity for medical devices in the Region of the Americas.
- Two new countries: El Salvador and Paraguay

# Regional Working Group meetings

- ✓ **Seven meetings: Cuba (2), Argentina, Brasil (2), USA, Colombia**
- ✓ **Last Regional Meeting of the Regulatory Authorities for the Strengthening of the Regulatory Capacity of Medical Devices in the Americas Region: October, 2015, in Colombia (3-day meeting; 47 participants from 14 countries; hosted by INVIMA)**
  - Training opportunities at the Regional level (INVIMA, CECMED, PAHO).
  - Presentation of the results of the pilot of advanced indicators in 5 countries (Colombia, Cuba, Ecuador, México, Panamá).
  - Analysis of the advanced indicators and the NRA Assessment Tool for Medical Devices.
  - Creation of a new technical group that will mirror the IMDRF Working Group on Software as a Medical Device.
  - Analysis of 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*” (National Regulatory Authority Report exchange criteria and report form).
  - Definition of the 2016 – 2017 Work Plan.



# Collaboration with IMDRF

- ✓ PAHO recognized as an affiliate organization in September 2014
- ✓ Regional Working Group meeting in conjunction with IMDRF meeting (Washington-DC, September 2014)
- ✓ Participation in the Tokyo and Kyoto meetings in 2015
- ✓ Creation of two Mirror Working Groups
- ✓ Regional Working Group meeting in conjunction with IMDRF meeting (Brasilia, March 2016), with the participation of 30 participants from 10 countries.



# Mirror Working Groups

- PAHO became an IMDRF Affiliate Organization in September 2014.
- The first concrete activity as part of this new interaction is the creation of working groups which mirror the IMDRF working groups on the following selected topics:

**MWG1:**  
NCAR  
Exchange  
Program

**MWG2:**  
Software as  
a Medical  
Device



# Mirror Working Group on the NCAR Exchange Program: REDMA Program

- The Secretariat is composed of regulatory officials from: Cuba (CECMED), Brazil (ANVISA) and Colombia (INVIMA).
- 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 the members of the Secretariat for their input. A second version of the document was analyzed during the 4th Regional Meeting in Bogota and later shared between the Working Group (16 countries) for their input.
- The final version of the document was developed based on comments received and shared with the Working Group.
- The “Secretariat functions of the REDMA program” draft document was prepared and presented at the meeting in Brasilia (March 7-8).
- Training activities are being scheduled.



# Mirror Working Group on “Software as a Medical Device”

- Topic identified as a priority for the Regional Working Group during the 4<sup>th</sup> Regional Meeting in Bogota, Colombia.
- The participants agreed on the creation of this MWG.
- The Secretariat was established and is composed of: ANMAT (Argentina), CECMED (Cuba) and MoH Uruguay.



# Technical Group on “Reprocessing of Single-Use Devices”

- During the 4<sup>th</sup> Regional Meeting in Bogota, Colombia, the Regional Working Group decided to create this Technical Working Group based on the identified priorities.
- The Secretariat was established and is composed of: INVIMA (Colombia), ANVISA (Brazil) and DIGEMID (Peru).

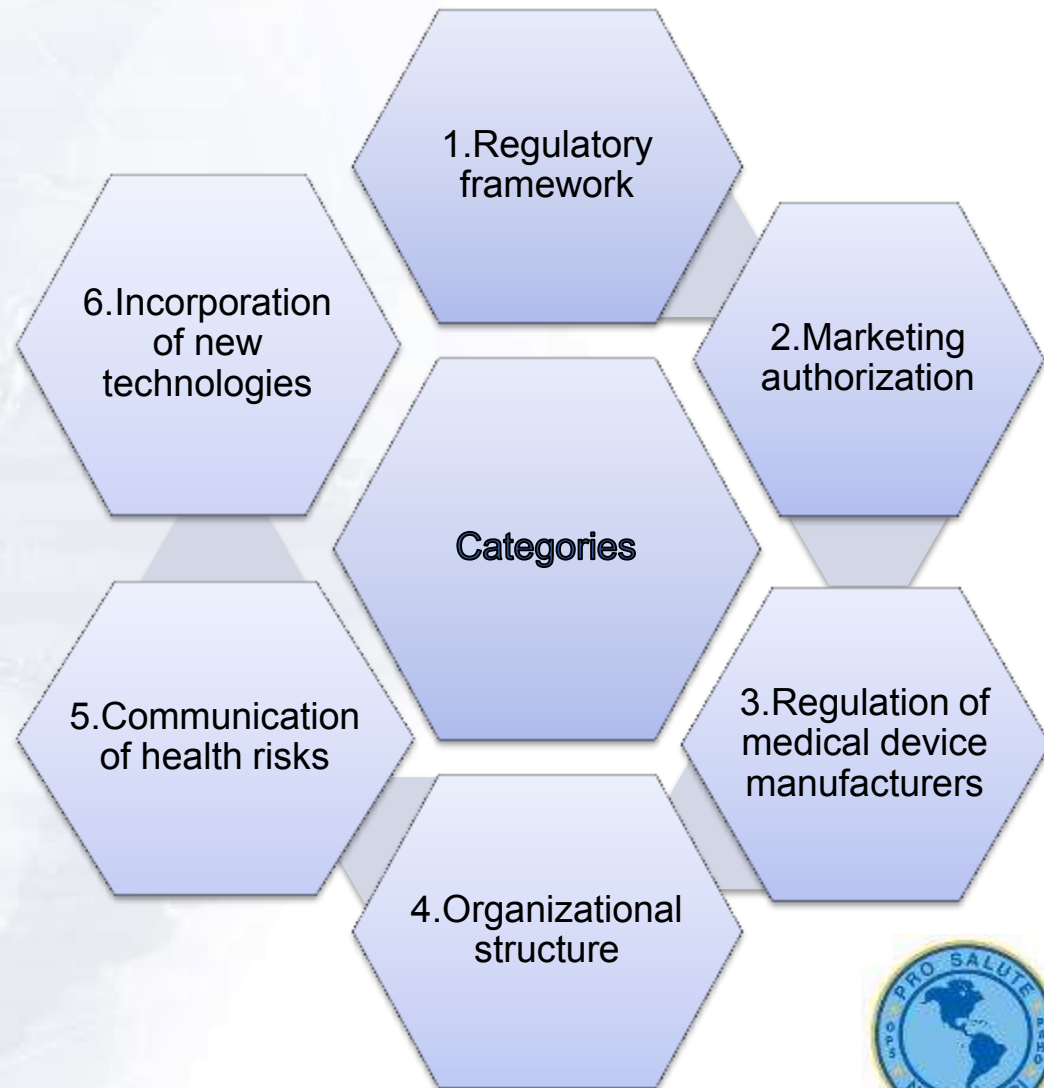





# Regional Mapping on the Regulation of Medical Devices

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

**SURVEY:** Structured in 6 categories, with 45 questions.



# Medical Devices Observatory on PRAIS



Regional Platform on  
Access and Innovation  
for Health Technologies **PRAIS**

Welcome, Nilda ▾


HOME COMMUNITIES REPOSITORY MEDICINES **MEDICAL DEVICES** RADIOLOGY BLOOD HTA


Your are at: Homepage > Medical devices observatory > **Standard report**

## Medical devices observatory


**STANDARD REPORT** Filter ▾

**GOVERNANCE**

1107 - Is there an institution responsible for the regulation of medical devices? 

1108 - Are there working alliances with other countries to strengthen the regulatory capacity for medical devices? 

**LEGAL BASIS**

1100 - Are there legal provisions establishing the attributions of the institution responsible for the regulation of medical devices? 

# Assessment Tool

**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 (3<sup>rd</sup> 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

- Argentina
- Brazil
- Canada
- Chile
- Colombia
- Costa Rica
- Cuba
- Dominican Republic

- Ecuador
- Honduras
- Mexico
- Panama
- Peru
- Uruguay

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
- Costa Rica
- Cuba
- Dominican Republic

- Ecuador
- Honduras
- Mexico
- Panama
- Peru
- Uruguay
- EUA
- OMS

**NEXT STEPS:** (1) Methodology of application based on technical sheets per indicator (2) To unify the PAHO and WHO assessment tools.



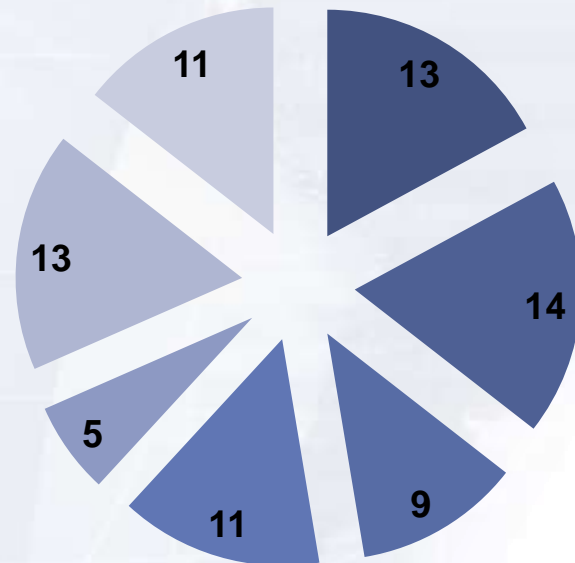
# Pilot Assessment

- Performed with 5 voluntary countries: Colombia (INVIMA), Cuba (CECMED), Ecuador (ARCSEA), México (COFEPRIS) and Panama (Ministry of Health).
- The 2nd version of the Assessment Tool was evaluated.
- The results of the pilot study were presented during the IV Regional Meeting in Bogota, Colombia (October 2015)



# Criteria of evaluation

- ✓ **CRITICAL:** Has been assigned to those indicators of the tool whose noncompliance may affect to a critical degree the regulatory system and/or the proper performance of critical control functions. It must be performed in an absolute and unquestionable manner for the positive evaluation of the NRA. Noncompliance or partial compliance with one of the factors that have a critical impact implies negative evaluation for that indicator and for the overall result of the NRA. Consequently, this will involve submitting a new request for evaluation within a certain time, established according to the critical problem identified.

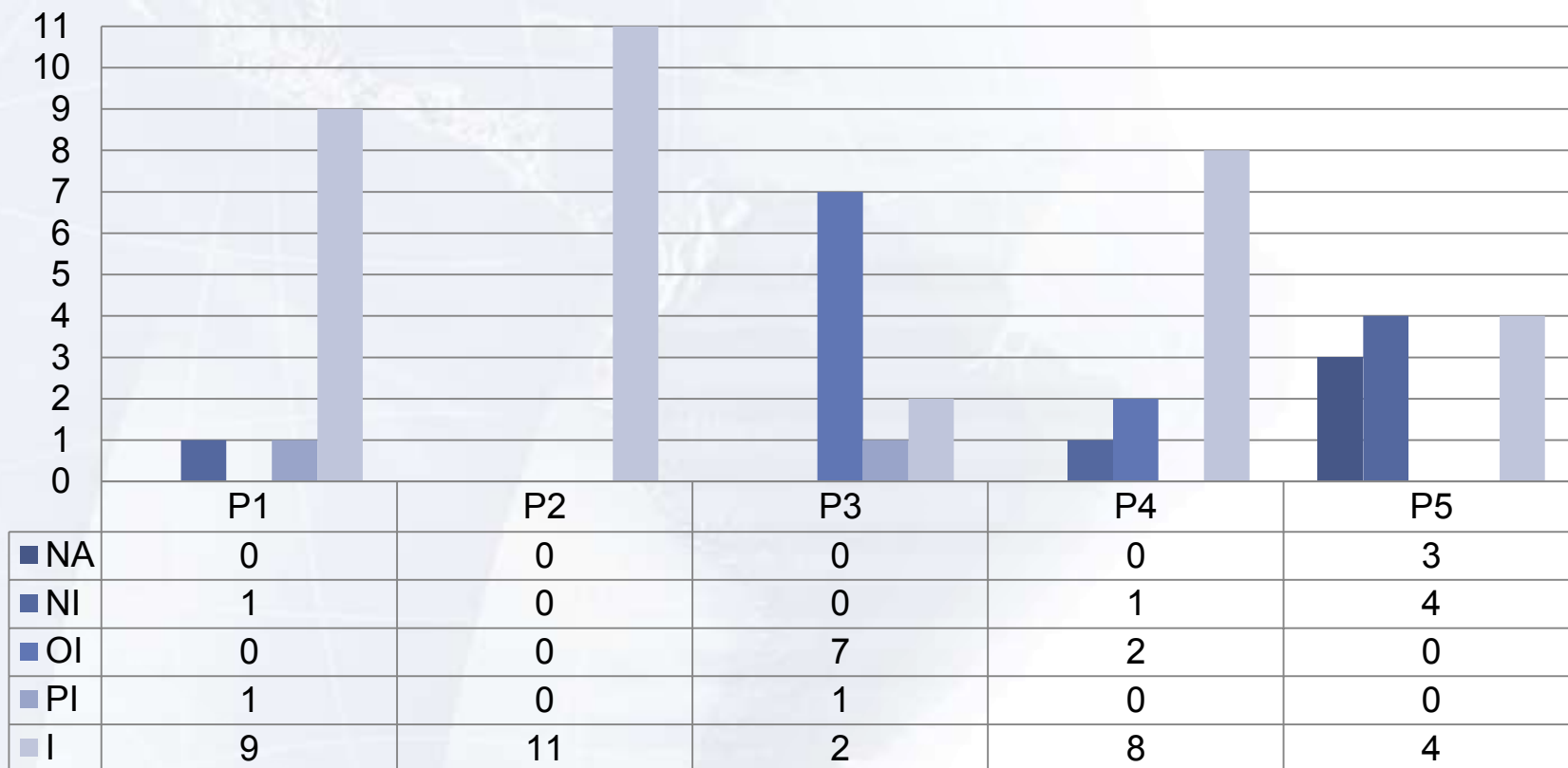


- Module 1
- Module 2
- Module 3
- Module 4
- Module 5
- Module 6
- Module 7



# Module 4. Post-marketing surveillance

## Module 4 - Critical



**NA** – Not Applicable

**PI** – Partially Implemented

**NI** – Not Implemented

**I** - Implemented

**OI** – Ongoing Implementation



# Conclusion of the pilot assessment

- The pilot study had a very positive feedback from the countries.
- It is necessary to agree on the terminology, methodology of application, scope in each country and professional training.
- Based on the comments received, in some cases, it is necessary to include more indicators in order to make them more specific individually.
- The Assessment Tool allows to identify gaps, which is essential to the development of strategies for bridging those gaps, strengthening national regulatory capacity in the Region





# Next steps

- To seek convergence between the PAHO assessment tool and the WHO assessment tool
- Approve final version of the background document on the NCAR mirror working group and implementation plan.
- Develop the Regional Regulatory Profile
- Definition of the training activities for the REDMA Program
- To launch the “Medical devices observatory” within PRAIS.
- Next Regional Meeting on Regulation of Medical Devices in Mexico (October 2016), in conjunction with the PANDRH meeting

