



Regulation of Medical Devices: a Regional approach



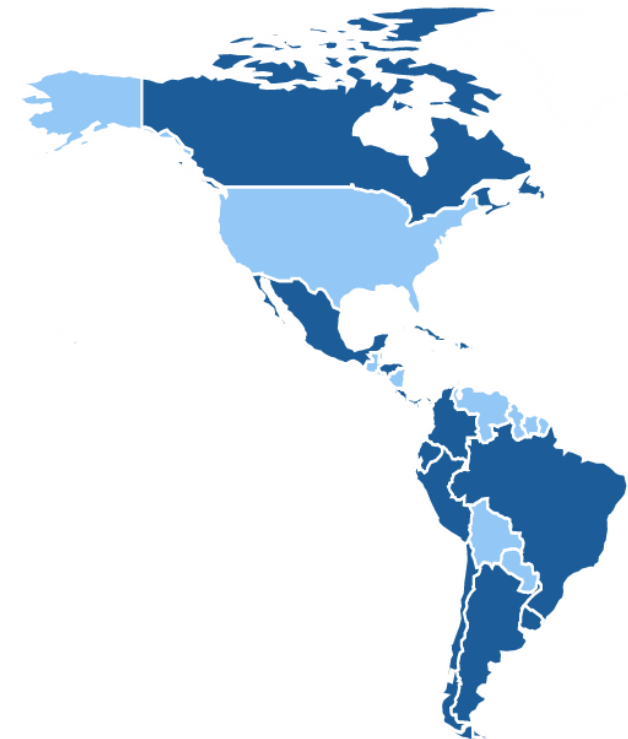
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**IMDRF Meeting
Tokyo, March 2015**

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.
 - ✓ Funded by ANVISA

- ❖ **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 (funded by US FDA, Health Canada and ANVISA)
 - ✓ Designation of PAHO as an IMDRF Affiliate Organization.

- ❖ **4th Regional Meeting to be held in Bogota, Colombia (October 2015)**



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 working groups that will mirror the IMDRF working groups on selected topics. Among the topics that are under discussion by IMDRF members, the Regional Group has been discussing the creation of two working groups:
 - Software as a Medical Device
 - NCAR Exchange Program



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 exchange among countries
- ✓ Very positive feedback from the Working Group

❖ **Online introductory course on Medical Devices 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 University of Vermont
- 52 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

-18 selected

-Participants from 9 countries:

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



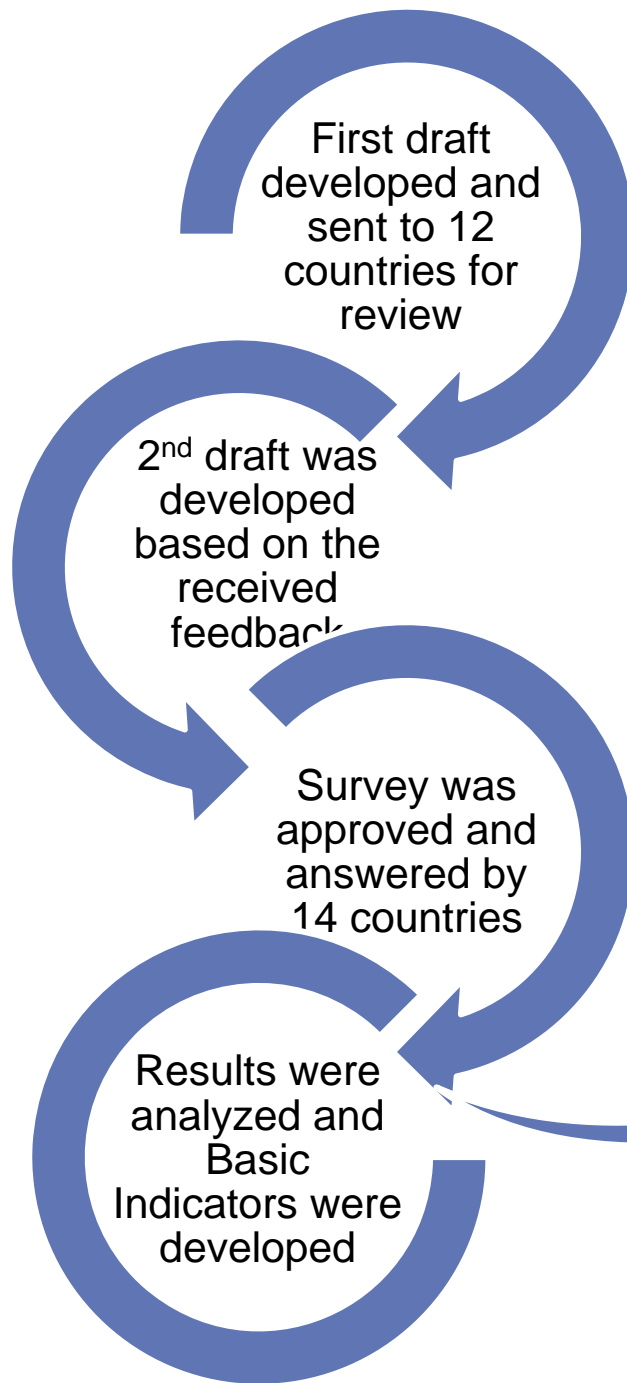
Regional Mapping on the Regulation of Medical Devices

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

SURVEY: It was developed in collaboration with Ministry of Health of Uruguay.

- It is structured in **6 main categories**.
- It consists on **45 questions**.





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



Basic Indicators

1100 Is there an institution responsible for regulating medical devices?

1101 Are there regulations establishing the attributions of the institution responsible for the regulation of medical devices?

1102 Is there a process for the registration of Medical Devices?

1103 Are Medical Devices being categorized by risk for registration purposes?

1104 Is there an Official Nomenclature System for Medical Devices?

1105 Are there regulations establishing the attributions of the institution responsible for the post-marketing vigilance of medical devices?

1107 Are there regulations related to the donations of medical devices?

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

1109 Are there specific policies to regulate the incorporation of new technologies and the acquisition of strategic products?



Results (1)

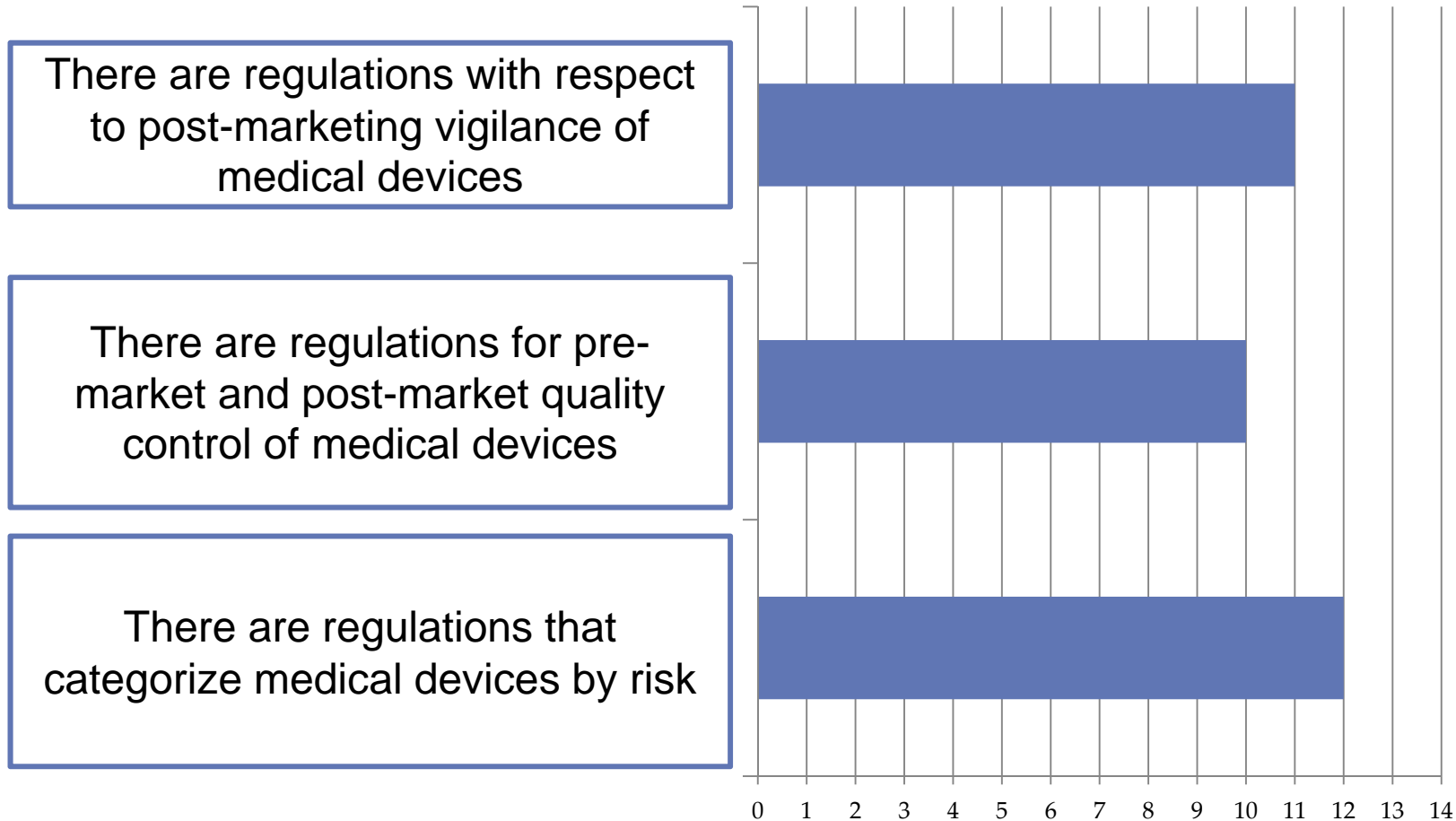
| Indicadores | % of achievement |
|---|------------------|
| 1100- Is there an institution responsible for regulating medical devices? | 93 |
| 1101- Are there regulations establishing the attributions of the institution responsible for the regulation of medical devices? | 93 |
| 1102- Is there a process for the registration of Medical Devices? | 93 |
| 1103- Are Medical Devices being categorized by risk for registration purposes? | 86 |
| 1105- Are there regulations establishing the attributions of the institution responsible for the post-marketing vigilance of medical devices? | 79 |
| 1104- Is there an official Nomenclature System for Medical Devices? | 71 |
| 1107- Are there regulations related to the donations of medical devices? | 64 |
| 1108 - Are there working alliances with other countries to strengthen the regulatory capacity for medical devices? | 43 |
| 1109 - Are there specific policies to regulate the incorporation of new technologies and the acquisition of strategic products? | 36 |

Results (2)

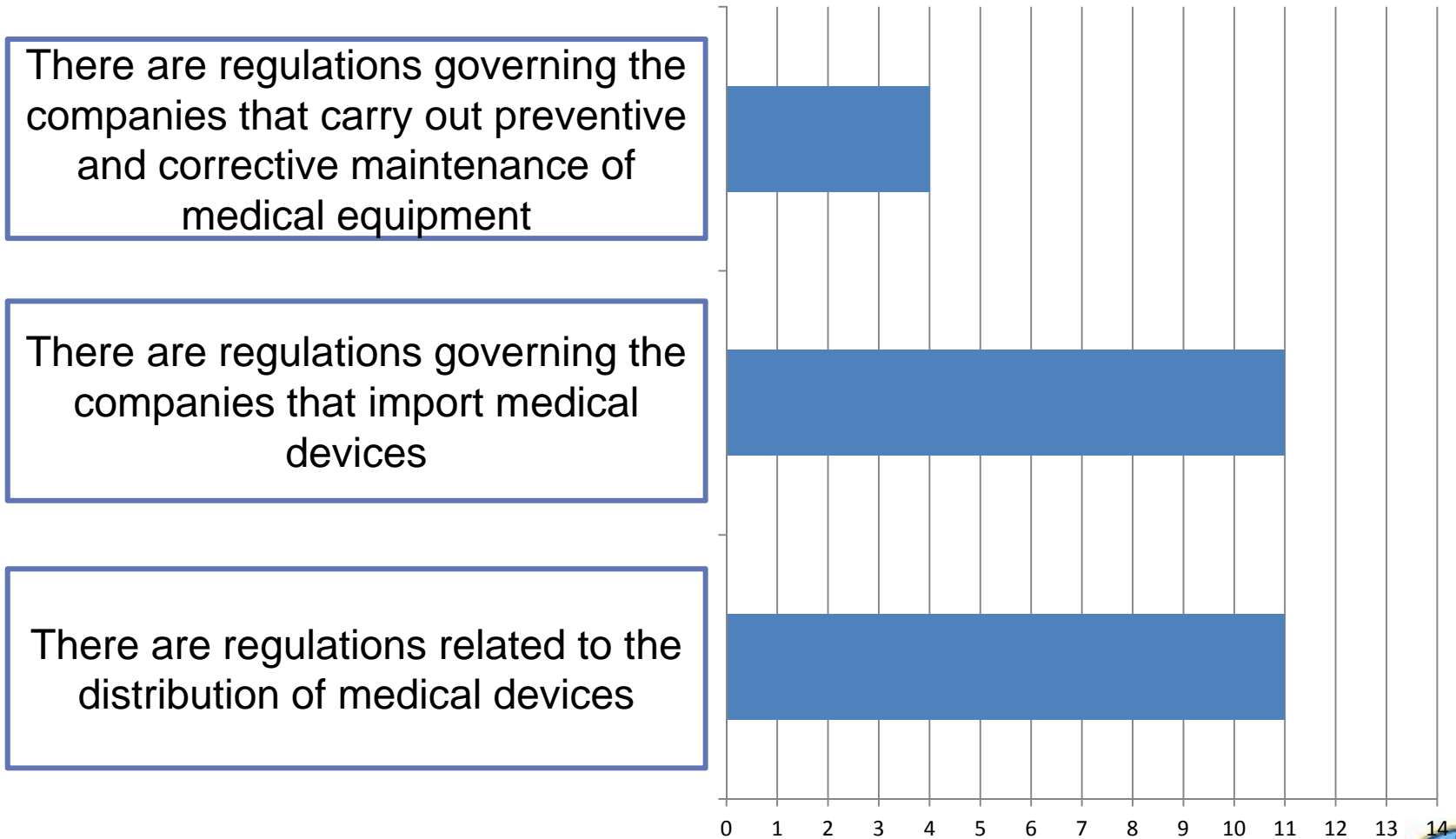
| Country | % of achievement – basic indicators |
|---------|-------------------------------------|
| A | 100 |
| B | 100 |
| C | 90 |
| D | 90 |
| E | 90 |
| F | 90 |
| G | 78 |
| H | 78 |
| I | 78 |
| J | 56 |
| K | 56 |
| L | 56 |
| M | 56 |
| N | 11 |



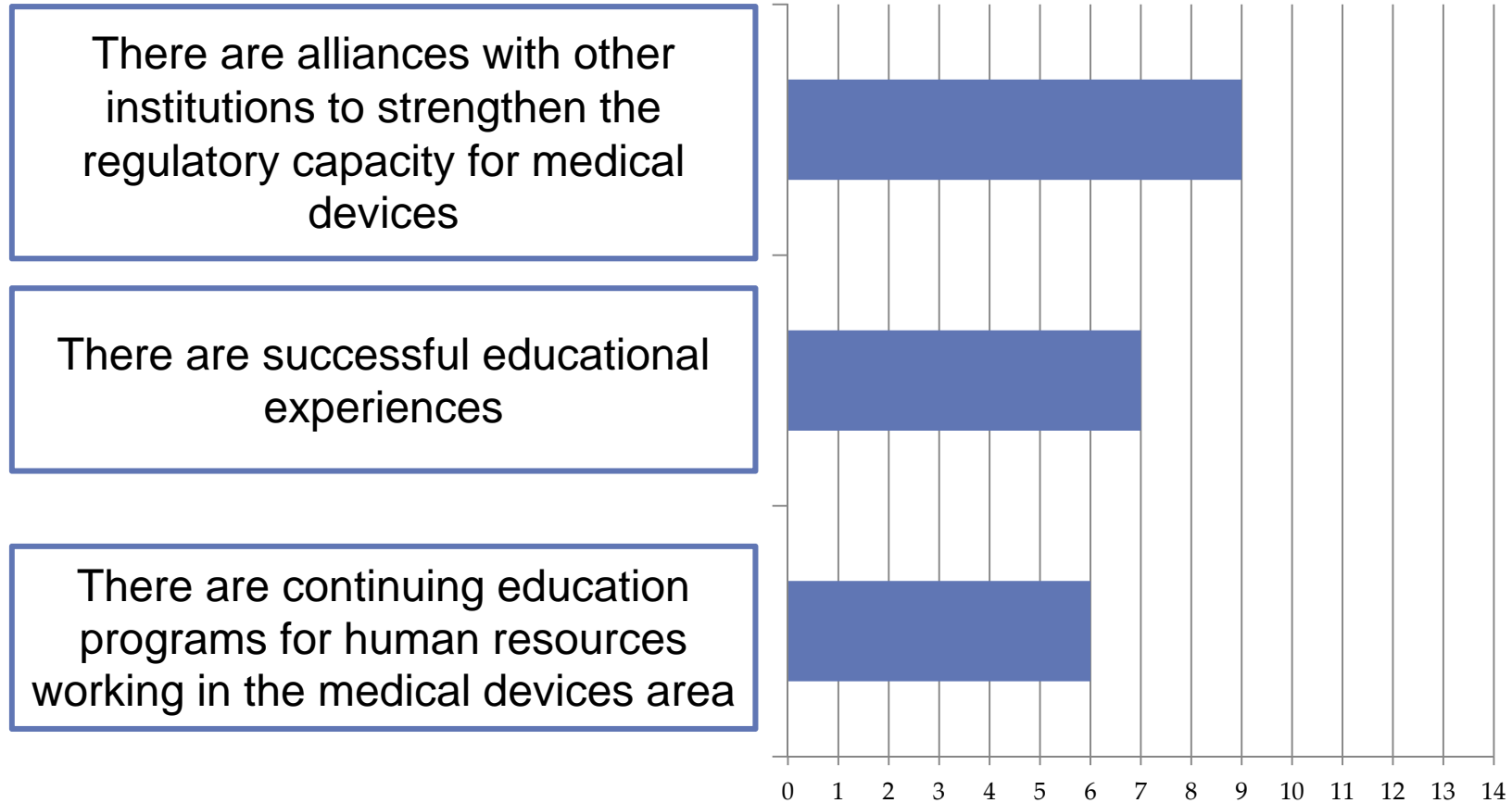
Results (3)



Results (4)



Results (5)



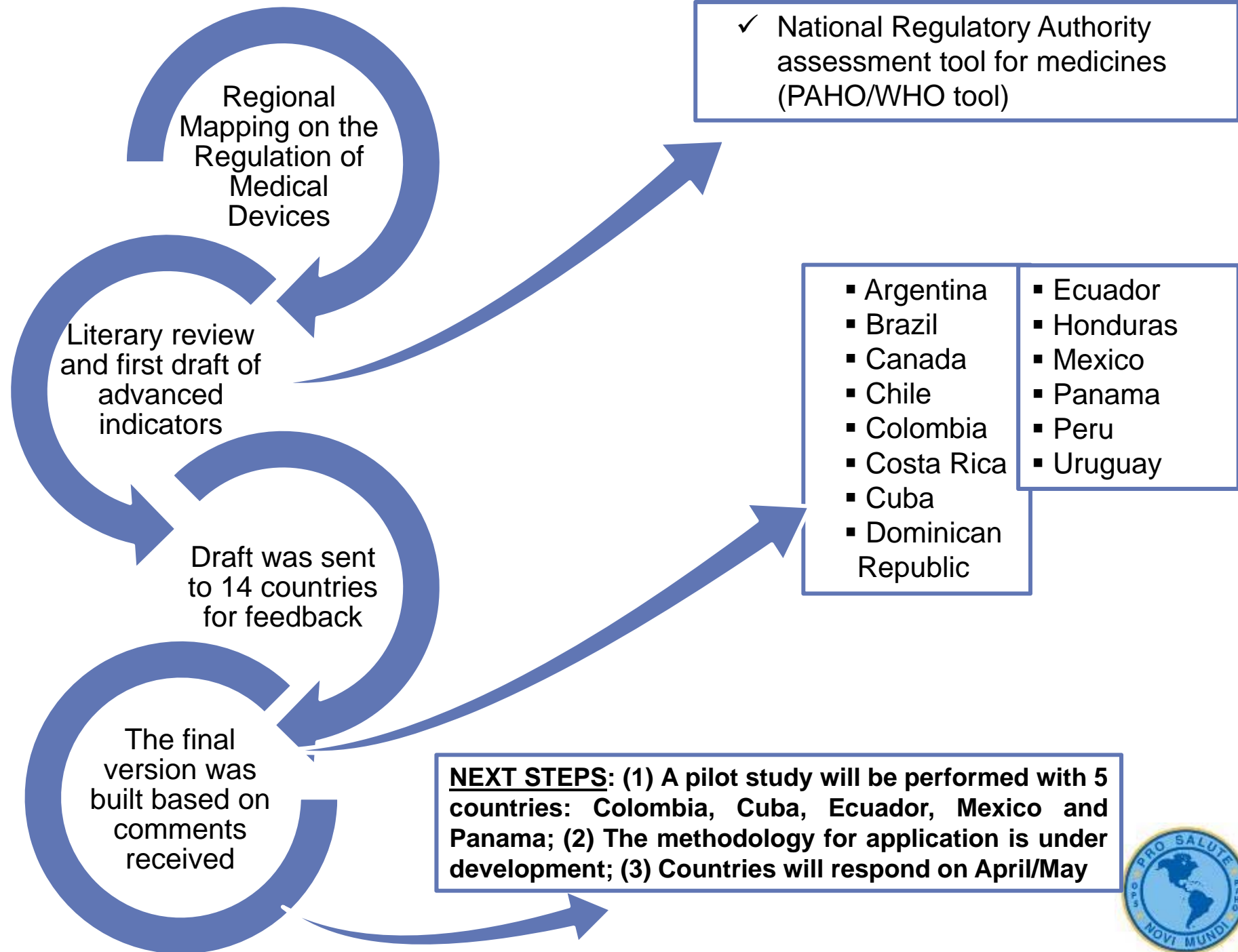
Advanced indicators

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 in **107 indicators**





Advanced Indicators (proposal)

| INDICADOR | NP | NI | EI | PI | I | OBSERVACIONES |
|---|----|----|----|----|---|---------------|
| 1.1 MODULO # 1 SISTEMA REGULADOR | | | | | | |
| Organización y estructura | | | | | | |
| 1.1.1 La regulación sanitaria se encuentra bajo la jurisdicción del Ministerio de Salud INFORMATIVO | | | | | | |
| 1.1.2 Las actividades de Regulación son organizadas y desarrolladas a nivel central del país. INFORMATIVO | | | | | | |
| 1.1.3 Si existen actividades descentralizadas a cargo de otras autoridades éstas siguen los mismos estándares, lineamientos y procedimientos CRITICO | | | | | | |
| 1.1.4 Si existe más de un organismo/ autoridad involucrada en la regulación, la legislación proporciona y define canales claros de coordinación entre los mismos y el respectivo empoderamiento CRITICO | | | | | | |
| 1.1.5 En caso de descentralización, está establecido e implementado un mecanismo de intercambio de información de forma que el organismo descentralizado recibe los requisitos y/o directivas e informes de la autoridad central y le envía sus informes a la misma CRITICO | | | | | | |
| 1.1.6 La Autoridad Reguladora tiene implementado un sistema de gestión de calidad (SGC) para todos los procesos reguladores NECESARIO | | | | | | |
| 1.1.7 La ARN utiliza expertos externos en sus procesos reguladores NECESARIO | | | | | | |
| 1.1.8 La ARN mantiene independencia respecto de investigadores, productores, distribuidores, y suministradores de dispositivos médicos CRITICO | | | | | | |
| 1.2 Bases legales | | | | | | |
| 1.2.1 La legislación define la creación de la ARN, su misión, términos de referencia, así como también su alcance, funciones y responsabilidades CRITICO | | | | | | |
| 1.2.2 El desarrollo de las regulaciones involucra a la Autoridad Reguladora a cargo de su implementación y cumplimiento. CRITICO | | | | | | |
| 1.2.3 Las regulaciones son aprobadas y publicadas oficialmente CRITICO | | | | | | |
| 1.2.4 Las bases legales específicas de la ARN le confieren la autoridad para realizar las inspecciones en los establecimientos donde se realicen o pretendan realizar actividades relacionadas con los dispositivos médicos regulados y para designar inspectores para conducirlos | | | | | | |

Next steps

- ❖ Launch the mirror working groups
- ❖ Pilot of advanced indicators in 5 countries
- ❖ Integrate the indicators in a WHO/PAHO assessment tool
- ❖ Develop the Regional Regulatory Profile
- ❖ Launch the Technovigilance course (INVIMA) in the Virtual Campus
- ❖ 2015 meeting of the working group in Bogota, Colombia, to be hosted by INVIMA
- ❖ 2016 meeting of the working group in conjunction with the IMDRF meeting in Brazil, to be hosted by ANVISA