

Update on the Regional Working Group



Pan American
Health
Organization



World Health
Organization

REGIONAL OFFICE FOR THE Americas

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IMDRF Meeting
Vancouver, Canada
14 – 16 March 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)

- ✓ **6 Regional Annual meetings: Cuba (2012), Argentina (2013), USA (2014), Colombia (2015), Brazil (2016) and Mexico (2016)**
- ✓ **Last Regional Meeting: October, 2016, Ciudad de Mexico (45 participants from 17 countries; hosted by COFEPRIS)**
 - 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



Update on the Working Groups

	Topic	Secretariat	New activities
Mirror Working Groups	REDMA Program	Cuba (CECMED) Brazil (ANVISA) Colombia (INVIMA)	<ul style="list-style-type: none"> ➤ Software development for the REDMA Program - <i>REDMA Web System</i> ➤ Pilot activity with 10 countries
	Software as medical devices	ANMAT (Argentina) CECMED (Cuba) COFEPRIS (Mexico) MoH (Uruguay)	<ul style="list-style-type: none"> ➤ 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)	<ul style="list-style-type: none"> ➤ 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

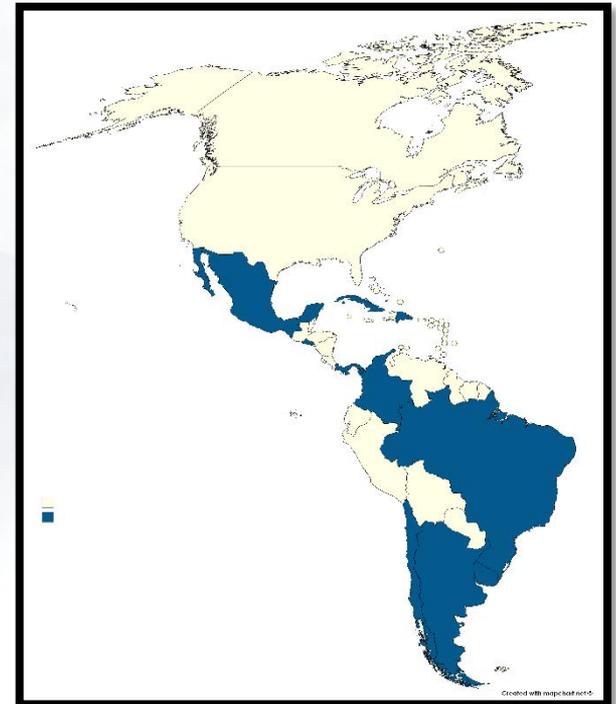


The screenshot shows the REDMA login page. At the top, the REDMA logo is displayed. Below it, the text 'Introduzca sus credenciales' is shown with a key icon. There are two input fields: 'Correo Electrónico' and 'Contraseña'. Below the 'Contraseña' field is a checkbox labeled 'Recordarme'. A blue button labeled 'Entrar' is positioned to the right of the 'Recordarme' checkbox. At the bottom of the page, there are two links: 'Olvidé mi Contraseña' and 'Regístrame'.



REDMA Web System – Pilot Activity (1)

- **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



REDMA Web System – Pilot Activity (2)

<p>PROGRAMA REDMA</p> <p>REDMA 04: 2017</p> <p>PROGRAMA REDMA</p> <p>“PROTOCOLO PARA LA PRUEBA PILOTO DEL SISTEMA WEB REDMA”</p> <p>Centro Colaborador OMS/OPS para la Regulación de las Tecnologías de Salud</p>	<p>PROGRAMA REDMA</p> <p>REDMA 03:2016</p> <p>Programa REDMA:</p> <p>Manual de Usuario del Sistema Web REDMA</p> <p>Centro Colaborador OMS/OPS para la Regulación de las Tecnologías de Salud</p>
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- **Documents shared:**
 - ✓ Protocol of action
 - ✓ User manual
 - ✓ Declaration of conformity
 - ✓ List of participants
 - ✓ REDMA Web System URL

DECLARACIÓN DE CONFORMIDAD PARA LAS AUTORIDADES REGULADORAS PARTICIPANTES EN EL PROGRAMA REDMA

- PAHO is working together with BIREME and CECMED so that in the coming months the REDMA Web System will be integrated within PRAIS



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PRAIS



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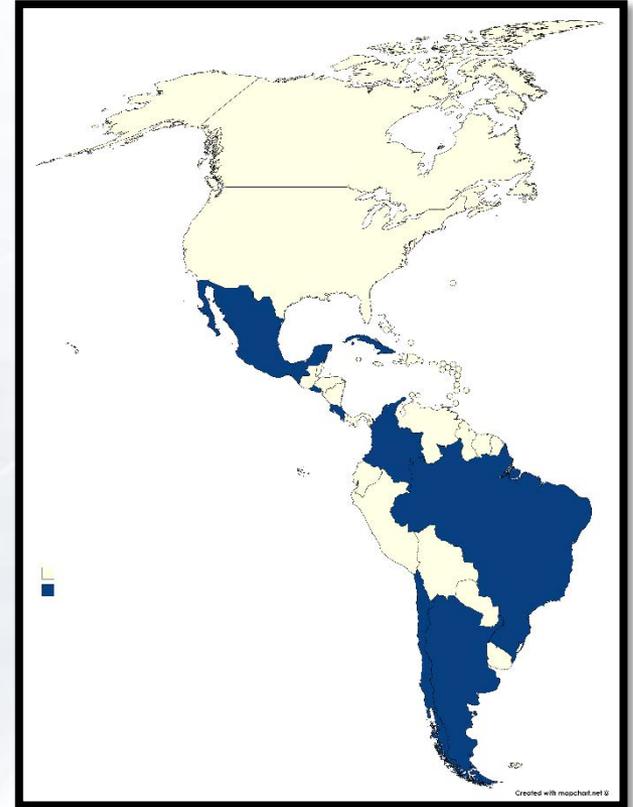
REDMA Web System – Pilot Activity ⁽³⁾

- Protocol of action**

Responsible	Activity	Date	Status
Coordinator	Design of the protocol and documents sent to the Secretariat for feedback	December 8th, 2016 – January 10th, 2017	Completed
Secretariat	WebEx exchange and approval of documents	February 7th, 2017	Completed
Secretariat	Convocation sent to pilot countries	February 13th, 2017	Completed
Secretariat	WebEx exchange within the secretariat and pilot countries	February 16th, 2017	Completed
Pilot countries	1st stage of the pilot activity	February 27th – March 10th, 2017	In Progress
Coordinator	Progress report	March 15th – March 17th, 2017	Not Started
Pilot countries	2nd stage of the pilot activity	March 20th – April 20th, 2017	Not Started
Coordinator	Progress report	April 26th – April 28th, 2017	Not Started
Pilot countries	Feedback of the pilot activity	April 17th – April 26th, 2017	Not Started
Coordinator	Conclude the final report	April 27th – May 12th	Not Started
Secretariat	Dissemination of the final report	May 15th – May 19th, 2017	Not Started

Mirror Working Group “Software as a Medical Device”

- A questionnaire (14 questions) for the analysis of the current regulatory situation in the Americas Region was developed by ANMAT and shared with the WG
 - At the moment, we received feedback from:
 1. ANMAT – Argentina
 2. ANVISA – Brazil
 3. ANAMED – Chile
 4. INVIMA – Colombia
 5. MoH - Costa Rica
 6. CECMED – Cuba
 7. DNM - El Salvador
 8. COFEPRIS – Mexico



- Results were presented and discussed during the 6th annual meeting of the Regional WG. The Secretariat will meet and discuss the next steps.



Technical Group “Reprocessing of Medical Devices” ⁽¹⁾

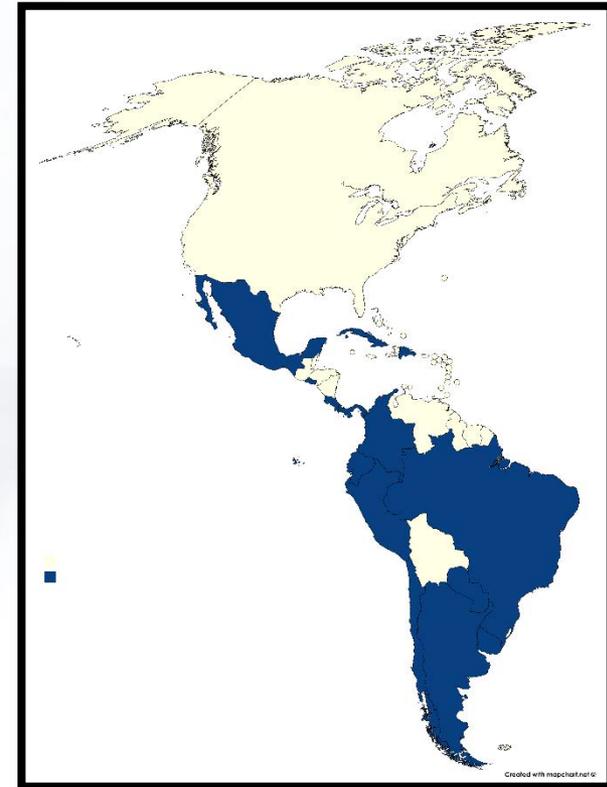
- A mapping activity on the Regulation of the Reprocessing and Reuse of Medical Devices in the Americas Region was held
- Assessment tool
 - Consists of 16 questions divided into 3 main categories:
 1. Structure of the Sanitary Regulation on Reuse and Reprocessing of Medical Devices in the country
 2. Regulation of Reuse and Reprocessed Medical Devices
 3. Regulation of companies/establishments of Medical Devices
 - Feedback from 14 countries
 1. Argentina
 2. Brazil
 3. Chile
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 6. Cuba
 7. Dominican Republic
 8. Ecuador
 9. El Salvador
 10. Mexico
 11. Panama
 12. Paraguay
 13. Peru
 14. Uruguay

INSTRUMENTO PARA EL MAPEO SOBRE REUSO Y REPROCESAMIENTO DE DISPOSITIVOS MÉDICOS EN LA REGIÓN DE LAS AMÉRICAS	
DATOS PERSONALES DEL PROFESIONAL QUE RESPONDE ESTE DOCUMENTO	
1	Nombre
2	E-mail
3	Número telefónico y/o fax Institucional
4	Cargo que ejerce dentro de la Institución
DATOS DE LA AGENCIA REGULADORA O INSTITUCION QUE TIENE A SU CARGO LA REGULACIÓN Y CONTROL DE LOS DISPOSITIVOS MÉDICOS EN EL PAÍS	
1	Nombre de la AR o Institución
2	Dirección de la AR o Institución
3	Número telefónico y/o fax de la AR o Institución
4	Página web de la AR o Institución
5	Nombre(s) y correo electrónico de 1-2 persona(s) de contacto de la AR en el área de Dispositivos Médicos
ESTRUCTURA DE LA REGULACION SANITARIA DE REUSO Y REPROCESAMIENTO DE DISPOSITIVOS MÉDICOS EN EL PAÍS	
1	En su país, la regulación del reuso y reprocesamiento de Dispositivos Médicos incluye: (Marque con una cruz X)
	Buenas Prácticas de Manufactura de Dispositivos Médicos <input type="checkbox"/>
	Reuso de Dispositivos Médicos <input type="checkbox"/>
	Reuso de Dispositivos Médicos de un solo Uso <input type="checkbox"/>
	Reprocesamiento Dispositivos Médicos de un Solo Uso <input type="checkbox"/>
	Reprocesamiento Dispositivos Médicos Reutilizables <input type="checkbox"/>



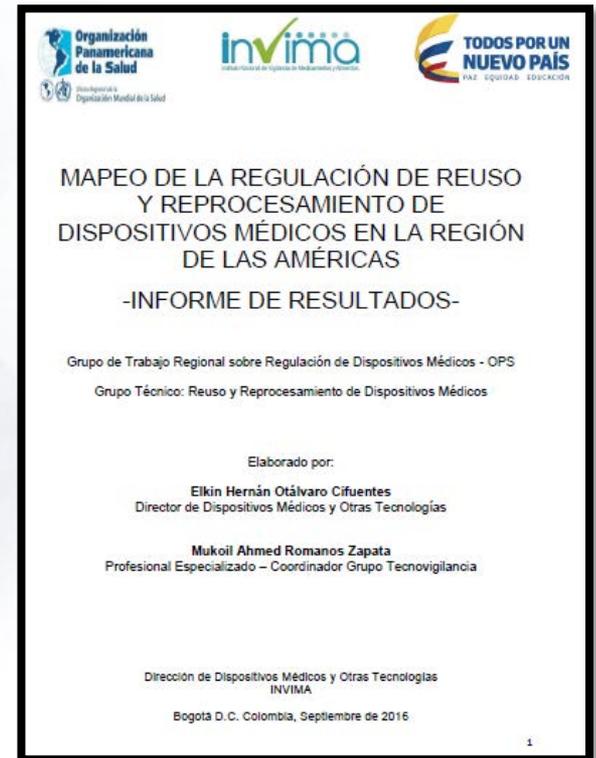
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Technical Group on “Reprocessing of Medical Devices” (2)

- The outcome report was elaborated by INVIMA and will be shared with the Regional WG. It includes:
 - Conceptual framework
 - International references
 - Medical Device Reprocessors – Private organizations
 - Mapping of the Regulation of reuse and reprocessing of medical devices in the Region of the Americas
 - Aspects related to the reuse of Medical Devices
 - Aspects related to the reprocessing of medical devices
 - Conclusions
 - Recommendations
 - Bibliography



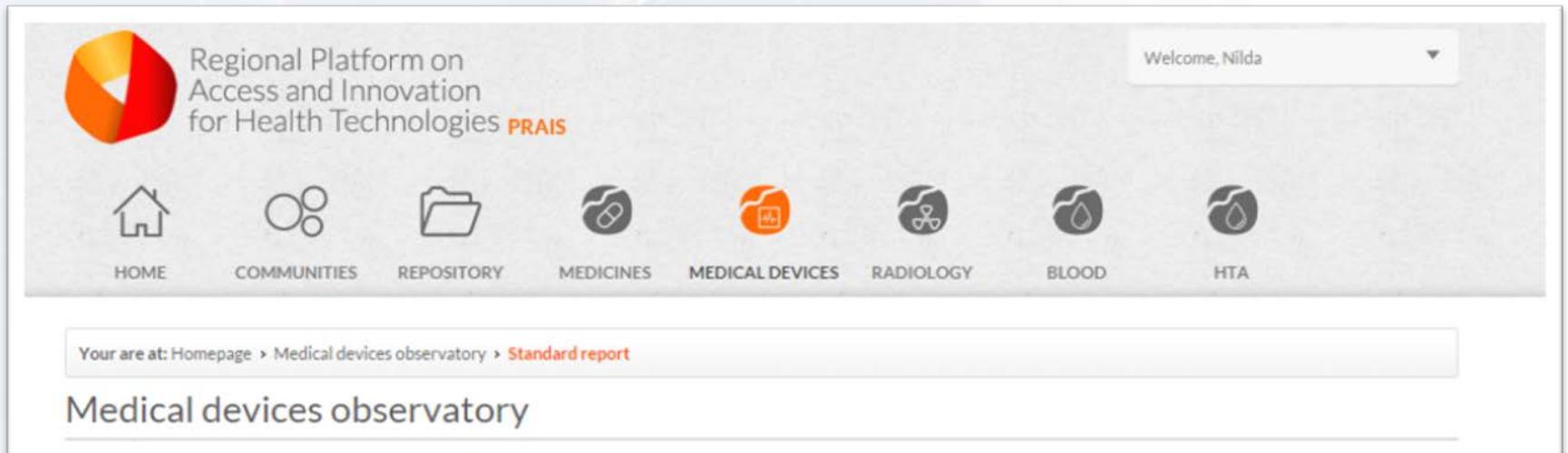
Virtual Training

- 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



Basic indicators

- **Objective:** Review, update, and adjust the medical devices' basic indicators
- In collaboration with PANDRH:
 - ✓ Update of basic indicators for the countries of the Regional WG
 - ✓ Extend the mapping for the 35 countries in the Region of the Americas
- Results will be posted on the Medical Devices Observatory within PRAIS



The screenshot displays the user interface of the PRAIS Medical Devices Observatory. At the top left is the PRAIS logo, a stylized globe in orange and red, followed by the text "Regional Platform on Access and Innovation for Health Technologies PRAIS". In the top right corner, a user profile dropdown menu shows "Welcome, Nilda" with a downward arrow. Below the header is a navigation bar with eight icons and labels: HOME (house icon), COMMUNITIES (two circles icon), REPOSITORY (folder icon), MEDICINES (pill icon), MEDICAL DEVICES (orange square with white icon), RADIOLOGY (circular icon with three lines), BLOOD (blood drop icon), and HTA (water drop icon). Below the navigation bar is a breadcrumb trail: "Your are at: Homepage > Medical devices observatory > Standard report". The main heading "Medical devices observatory" is displayed below the breadcrumb trail.



Advanced indicators –Assessment Tool (1)

- ✓ Self-assessment of INVIMA-Colombia, CECMED-Cuba, ARCSA-Ecuador, COFEPRIS-Mexico and MoH Panama self-assessed the 2nd version of the Assessment Tool
- ✓ The Regional WG concluded that the Assessment Tool contributes to the development of the NR Systems in the Americas Region. It allows to identify gaps which favor actions to improve NR Systems
- ✓ After the 5th Regional Meeting, the structure of the Assessment Tool changed into modules with indicators and sub-indicators and the 4th draft was built and shared with the WG for feedback
- ✓ Analysis of the sub-indicators: circulation of the 4th version and contributions received from 6 countries: Brazil, Chile, Colombia, Ecuador, El Salvador and Mexico
 - Identification of new sub-indicators
 - Criteria and methodologies for the evaluation of compliance with the sub-indicators
 - Conceptual criteria for determining the maturity level of the regulatory capacity of each NRA



Advanced indicators –Assessment Tool (2)

Next steps:

- Consensus on evaluative acceptance criteria and regulatory requirements as acceptable evidence during the assessment
- Determination of the classification levels resulting from assessments of regulatory capacity in each NRA
- Country self-assessment with the new version of the tool



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 – 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
- Continue with the training activities
- Develop guidelines for the reuse and reprocessing of medical devices
- 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

