IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

16:10 – 16:25

Pan American Health Organization (PAHO)

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European Commission

European Union

IMDRF International Medical Device Regulators Forum

Update from the Pan American Health Organization

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Regional Advisor, Health Technology Management

28 March 2023

Overview

1. Regional Working Group on Medical Devices Regulation

Regional Meeting

Collaboration with IMDRF

REDMA Program

Assistive Products (AP)

Advances in the Regulation of Medical Devices in Colombia

Advances in the Regulation of Medical Devices in Cuba

2. Policy to Strengthen National Regulatory Systems for medicines and other health technologies

3. Substandard and Falsified Medical Devices

4. In Vitro Diagnostics (IVDs)

REGIONAL WORKING GROUP ON MEDICAL DEVICES REGULATION

Regional Meeting

The *XI Meeting of Regulatory Authorities for the Strengthening of the Regulatory Capacity of Medical Devices in the Americas* will be held in October 2023 in El Salvador

Collaboration with IMDRF

IMDRF Working Groups

The participation of the members of the Regional Working Group is encouraged

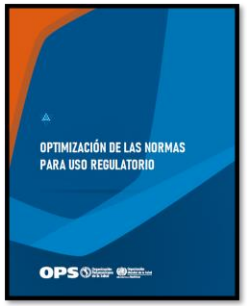
- Customized medical devices (ANMAT, Argentina)
- Artificial Intelligence (ANMAT, Argentina)
- Good Regulatory Review Practices (INVIMA, Colombia)

REGIONAL WORKING GROUP ON MEDICAL DEVICES REGULATION

Collaboration with IMDRF

Translations

12 IMDRF technical documents **published in Spanish**
3 IMDRF technical documents **published in Portuguese**
6 IMDRF technical documents in **technical review**



Dissemination of IMDRF technical documents

In collaboration with NRA of the Region, organization of webinars to share the content of the IMDRF technical documents translated into Spanish.

Document	NRA	Date	Attendance
Clinical Evidence - Key Definitions and Concepts *Evidencia Clínica. Principales definiciones y conceptos*	INVIMA	16 December 2022	**121** participants **19** countries
FIRST WEBINAR			

REGIONAL WORKING GROUP ON MEDICAL DEVICES REGULATION

Program to Exchange Adverse Event Reports For Medical Devices In The Americas (REDMA Program)

OBJECTIVES

- To exchange reports of adverse events or incidents from medical devices between the National Regulatory Authorities of the Americas Region
- To promote the development of vigilance systems

11
Associated members

BOL | ECU (2) | HND | NIC | PRY | ELS | URY | PAN | DOR | VEN

6
Full members

ARG | BRA | COL | CUB | CHL | MEX

39 Reports
26 confidential - 13 public

- Report source: Healthcare institutions 50% | manufacturers 37% | users 13%.
- Risk level of the devices reported: 38% Low-Moderated | 29% High | 21% Moderated-High | 12% Low.
- The most reported medical specialty was cardiovascular, representing 21%.

REGIONAL WORKING GROUP ON MEDICAL DEVICES REGULATION

Regulation of Assistive Products (AP) in the Americas

Main components	Activities
Assessment of the regulatory situation of Assistive Products in the Region	**Indicators on AP** • Completed desk research. Looking to validate results with Member States
Regulation of Assistive Products course	**To be develop this year** • Strengthening regulation of AP will be included in national rehabilitation and AT strategic plans of selected countries
Development of National Lists of Priority Assistive Products	**Indicators on AP** • Based on WHO APL second version and • National context and local priorities • To focus regulatory and quality assurance efforts in these AP

REGIONAL WORKING GROUP ON MEDICAL DEVICES REGULATION

Regulation of Assistive Products (AP) in the Americas

- Virtual Course: Introduction of Assistive Technology in the Americas

- 1529 participants, 28 countries
- 809 certified professionals
- Topic on strengthening regulation of AP is included
- English version coming soon
- **Join today and start improving access to AT!**

REGIONAL WORKING GROUP ON MEDICAL DEVICES REGULATION

Advances in the Regulation of Medical Devices in Colombia

Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA)

Resolution 1405/2022. Semantic standard and coding of medical devices
Resolución 1405/2022. Estándar semántico y codificación de dispositivos médicos

Resolution 214/2022. Dental personalized medical devices
Resolución 214/2022. Dispositivos médicos personalizados bucales

Law 2287/23. National Biobank System
Ley 2287/23. Sistema Nacional de Biobancos

Work in progress: National Policy of Medical Devices
Trabajo en proceso: Política Nacional de Dispositivos Médicos

Regulatory Impact Analysis (ex post evaluation) to assess relevance and areas for improvement of Decree 4725/2005 – Decree 3770/2004

Análisis de impacto normativo (evaluación ex post) para evaluar la pertinencia y las áreas de mejora del Decreto 4725/2005 – Decreto 3770/2004

ExAnte evaluation:
Clinical investigation with MD and IVD
Evaluación ExAnte:
Investigación Clínica con DM y RDIV

Lucia Ayala Rodríguez (layalar@invima.gov.co)
Technical Director of Medical Devices - INVIMA

REGIONAL WORKING GROUP ON MEDICAL DEVICES REGULATION

Advances in the Regulation of Medical Devices in Cuba

Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos (CECMED)

Regulation E106-22	Approved requirements for regulatory control of Diagnostic Ultrasound Systems
Resolution 181/22	Concentrated solutions for dialysis and components for their preparation, now regulated as medical devices
Regulation E102-22	Updated list of recognized standards to demonstrate compliance with essential principles
Regulation E103-22	Updated guideline for IVDs
Implementation of procedures for regulatory monitoring of processes related to domestically produced medical devices	
Expedited registration granted for more than 30 medical devices, including IVDs	
Redesignation as WHOCC the for Regulation of Health Technologies (2022-2026)	
Engagement in WHO activities	GMRF and HEARTS Initiative
Publications	• Contribution from Cuba to the regional strengthening of Medical Devices Regulation. PAHO, 120 years with Cuba (available in Spanish). • Overview of the regulatory requirements for medical devices, including in vitro diagnostics medical devices, in Cuba. Journal of Medical Devices Regulation

CSP30/11 POLICY TO STRENGTHEN NATIONAL REGULATORY SYSTEMS FOR MEDICINES AND OTHER HEALTH TECHNOLOGIES

STEPS UNTIL ADOPTION:

- Consultation sessions with Member States;
- PAHO internal review process;
- Edition and publication in all official languages;
- Executive Committee reviewed the Policy and adopted the proposed Resolution

The Policy was **adopted** at the **30th Pan American Sanitary Conference** on 29 September 2022

OBJECTIVE

Promote **efficient regulatory systems** in **all Member States**, tailored to the needs of their health systems, with a maturity level of 3 or higher in order **to ensure the quality, safety, and efficacy of health technologies**, in keeping with PAHO/WHO recommendations

In addition, where national policies are in place and the context permits, regulatory systems can help **foster the production of health technologies** that promote equitable access, health and well-being, and economic and social development.

CSP30/11 POLICY TO STRENGTHEN NATIONAL REGULATORY SYSTEMS FOR MEDICINES AND OTHER HEALTH TECHNOLOGIES

- Adopt sustainable State policies to strengthen the governance and stewardship of regulatory systems
- Promote the strengthening of regulatory systems to ensure consistent, transparent processes based on regulatory science
- Strengthening regulatory harmonization and convergence
- Adopt new evaluation systems based on the WHO Global Benchmarking Tool (GBT) and related mechanisms

CSP30/11 POLICY TO STRENGTHEN NATIONAL REGULATORY SYSTEMS FOR MEDICINES AND OTHER HEALTH TECHNOLOGIES

The policy urges the Member States, in keeping with their contexts and needs, to:
…

h) ***promote harmonization and regulatory convergence through participation in*** *PANDRH and* ***the international harmonization mechanisms recommended by the Pan American Health Organization (PAHO) and World Health Organization (WHO)*** *as sources of regulatory standards and good practices, including mechanisms such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), the* ***International Medical Device Regulators Forum (IMDRF)****, and the Pharmaceutical Inspection Co-operation Scheme (PIC/S);*

…

IN VITRO DIAGNOSTICS (IVDs)

1. Quality Assurance

- Development of eligibility criteria for non-WHO PQ IVDs

  - ✓ The IVD has been granted a market authorization by one of the following National Regulatory Authorities (NRAs): Stringent Regulatory Authorities recognized by WHO in the *Abridged Prequalification Assessment: Prequalification of In Vitro Diagnostics* and Regional National Regulatory Authorities currently members of the **International Medical Device Regulators Forum (IMDRF)**
  - ✓ The product is being commercialized in the country where the market authorization was granted

- QA for non-WHO PQ IVDs to respond to the needs of PAHO's Member States (for example: IVDs for chagas, leishmaniasis, etc)

IN VITRO DIAGNOSTICS (IVDs)

2. Webinars

More than 500 participants from over 25 countries attended the following webinars:

- WHO Essential Diagnostic List (EDL)
- Performance evaluation of In Vitro Diagnostics: Experience of the laboratories in the Region of the Americas
- Workshop on WHO prequalification of IVDs
- Workshop on WHO Emergency Use Listing for IVDs

3. Dissemination of WHO guidance documents

- Spanish and Portuguese translation of the document "Selection of Essential In Vitro Diagnostics at Country Level: Using the WHO Model List of Essential In Vitro Diagnostics to develop and update a national list of essential in vitro diagnostics".

SUBSTANDARD AND FALSIFIED (SF) MEDICAL DEVICES

1. Mapping of NRAs in the Region of the Americas

Review of **19** NRA websites:

✓ Legal provisions establishing the responsibility of NRAs to monitor SF MD were found in **11 countries**

Different terms and definitions were identified, for example: substandard, falsified, counterfeiting, quality failure, technical complaint, fraud, adulteration, alteration, product out of specification, illegitimate product, etc. (terms translated from Spanish and Portuguese)

2. Development of an operational regional framework to monitor SF Medical Devices in the Region of the Americas

✓ Coordination with WHO on SF medical devices activities:

- Elaboration of a **mini survey** on activities related to SF medical devices to be sent to the NRAs in the Americas
- Preparation of a **webinar on SF Medical Devices** to present the activities carried out by WHO and exchange experiences between NRA in the Americas

IMDRF International Medical Device Regulators Forum

Thank you!

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