IMDRF
International Medical Device Regulators Forum

EU2023
EUROPEAN UNION Chair

European Commission

European Union

15:25 – 16:55

Stakeholders Session

IMDRF International Medical Device Regulators Forum | EU2023 EUROPEAN UNION Chair

15:25 – 15:40

African Medical Devices Forum (AMDF)

Dimakatso Mathibe

Vice Chair, African Medical Devices Forum (AMDF)

European Commission | European Union

African Union Development Agency (AUDA-NEPAD)

World Health Organization

African Medical Devices Forum

International Medical Device Regulators Forum

Stakeholder Open Forum

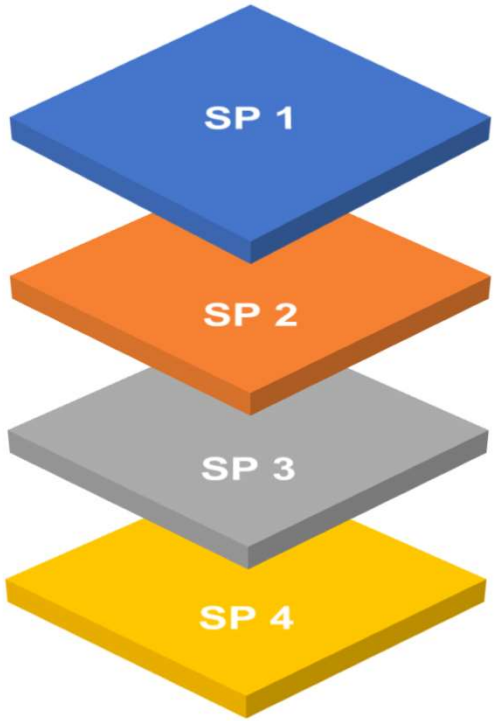
Dimakatso Mathibe
AMDF Vice-chair/SAPHRA SA

Brussels, Belgium
27 March 2023

AMDF Workplan 2023

Advance and promote African continent harmonization, mutual recognition, and reliance of medical devices regulations in Africa.

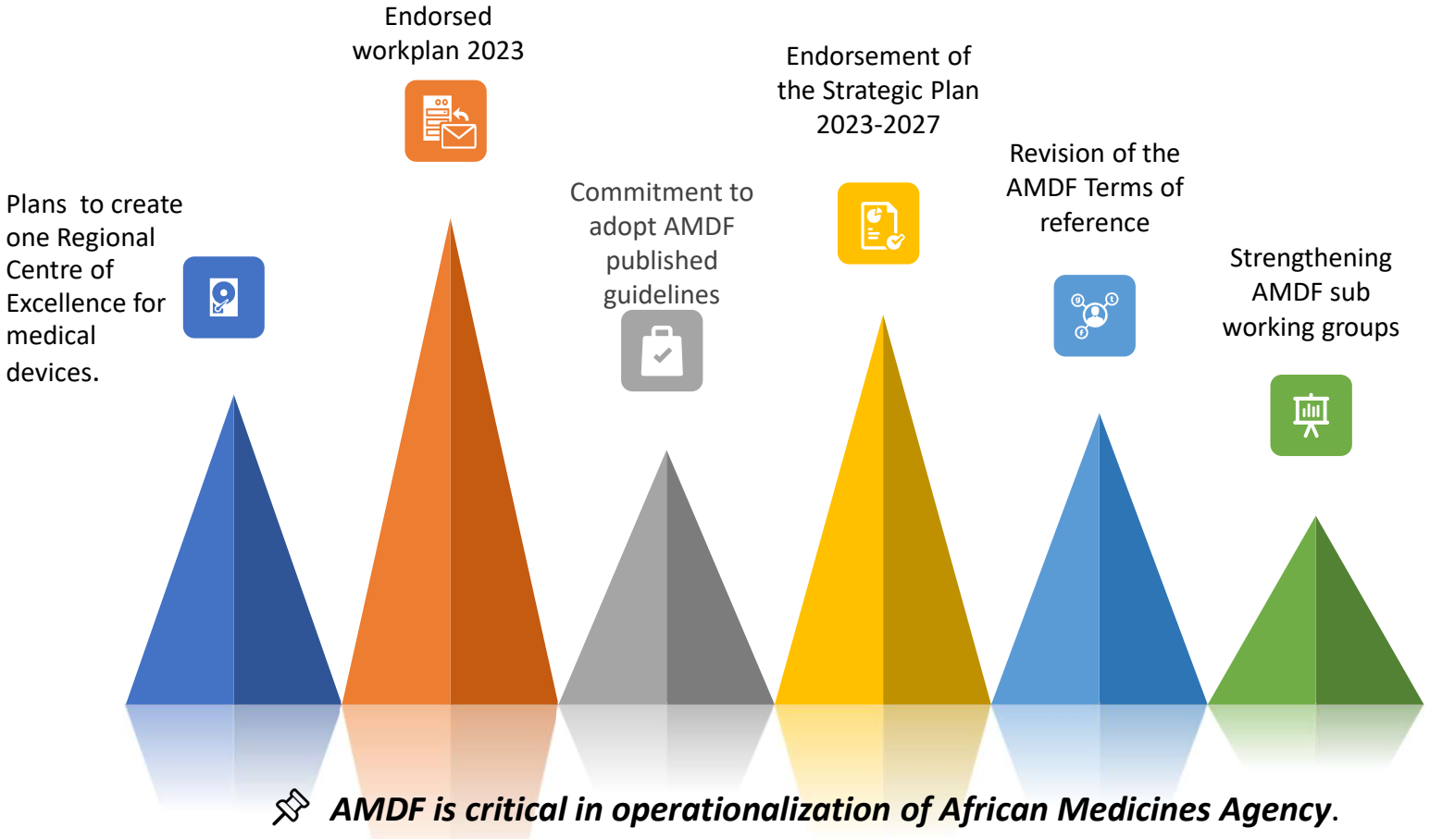
Advance the sensitization, adoption and roll out of AMDF strategic priorities across member states, partners, and stakeholders



Encourage innovation in medical devices including in-vitro diagnostics on the continent through local production of quality-assured essential medical devices and in-vitro diagnostics as sustainable path in ensuring self-reliance

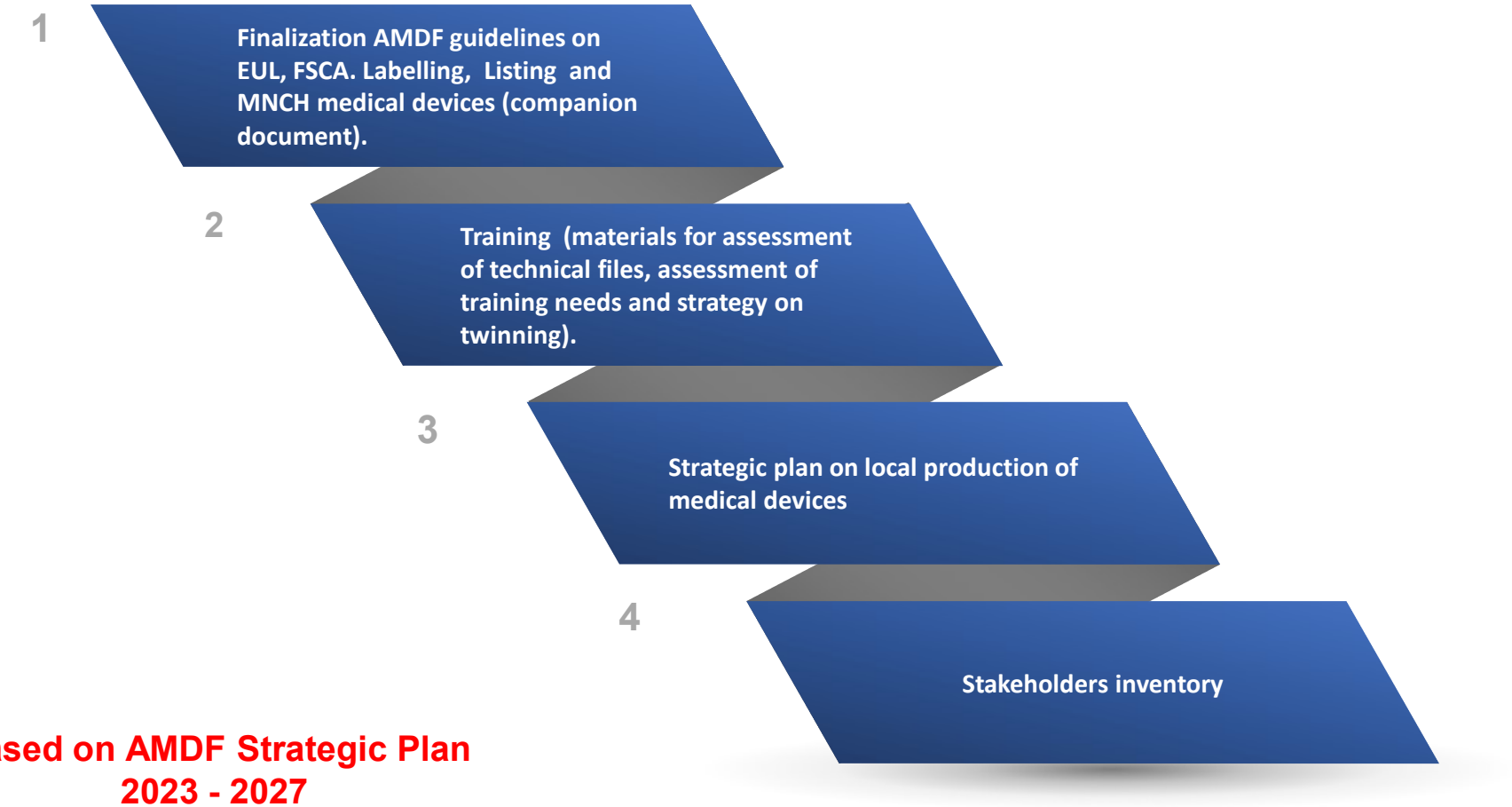
Continue to build technical capacity of national regulatory agencies in medical devices and IVDs regulatory frameworks, guidelines, and quality management systems

AMDF Technical Committee meeting in Accra, Ghana 6-7 December during AMRH week



AMDF is critical in operationalization of African Medicines Agency.

Planned output 2023



Based on AMDF Strategic Plan 2023 - 2027

Partner/Stakeholder support to AMDF

- AMDF is a key asset in the development of technical expertise for the AMA.
- Partners - WHO, MTaPS, FIND, ASLM, MDRC, USP - confirmed support for the strategic priorities of AMDF.
- Partnerships are being explored specifically with mature NRAs.
- Participation and alignment with global harmonization initiatives e.g. GHWP

Thank you!

African Medical Devices Forum

IMDRF International Medical Device Regulators Forum | EU2023 EUROPEAN UNION Chair

15:55 – 16:10

Global Harmonization Working Party (GHWP)

Xu Jinghe

Deputy Commissioner National Medical Products Administration (NMPA)

Chair, Global Harmonization Working Party (GHWP)

European Commission | European Union

IMDRF
International Medical Device Regulators Forum

EU2023
EUROPEAN UNION Chair

15:55 – 16:10

Asia-Pacific Economic Cooperation (APEC)

Cheng-Ning Wu

Senior Technical Specialist, Division of Medical Devices and Cosmetics, Taiwan Food and Drug Administration

European Commission

European Union

IMDRF International Medical Device Regulators Forum

Update on Medical Device PWA of RHSC

APEC Co-Champion Economies:

Japan – MHLW/PMDA

South Korea – MFDS

USA – FDA

APEC Asia-Pacific Economic Cooperation

IMDRF Stakeholder Open Forum 28 March 2023

Priority Work Areas (PWAs)

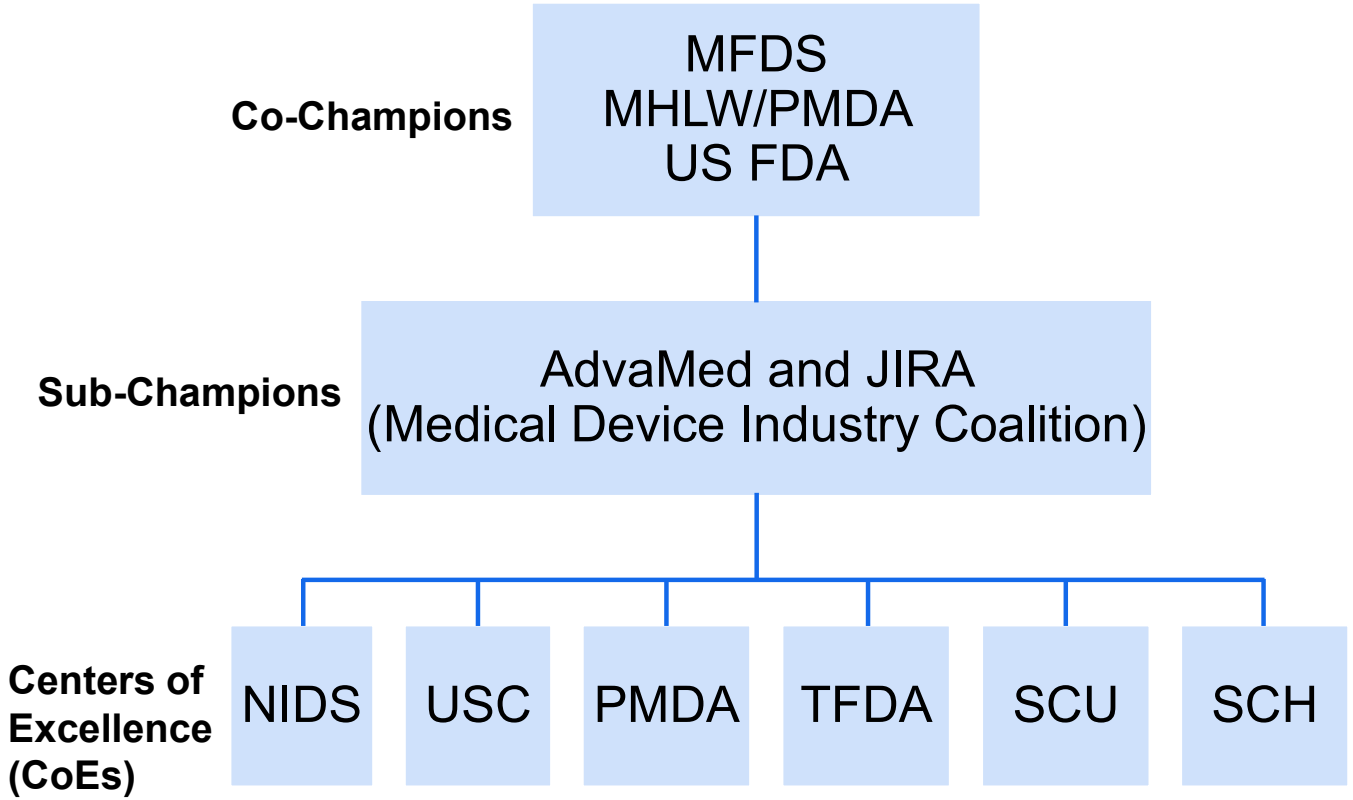
- Multi-Regional Clinical Trials and Good Clinical Practice Inspection (Japan, Thailand)
- Pharmacovigilance (Korea)
- Biotherapeutic Products (Current PWA Management: US, BIO)
- Advanced Therapy Products (Singapore, US)
- Good Registration Management (Chinese Taipei, Japan)
- Global Supply Chain Integrity (US)
- **Medical Device** (Japan, Korea, US)

Medical Device PWA

Goals of PWA:

- Promote international harmonization initiatives (i.e., GHTF/IMDRF guidance documents)
- Build regulatory capacity and knowledge
- Support harmonized implementation efforts among APEC economies

Medical Device PWA Structure



Medical Device PWA Roadmap

- Promotes regulatory convergence for medical device regulatory systems
- Focuses on training and education efforts related to topics across the Total Product Life Cycle (TPLC) of medical devices:
  - Premarket
  - Postmarket
  - Quality Management System (QMS)

PWA Core Curriculum

- Annex to the PWA roadmap
- “Reference library” of harmonized guidance documents on TPLC topics
- Medical Device PWA includes specified GHTF/IMDRF documents
- Both medical devices and in vitro diagnostic (IVD) medical devices are inclusive
- Co-Champions continuously update Core Curriculum with intersessional approval

CoE Programs Held in 2022 since Last Open Forum

CoE	Economy	Program	Format	Date
SCH	Korea	2022 SCH APEC Medical Device CoE Training	In-Person & Virtual	Nov. 7 - 8 & Nov. 9 - 23
PMDA	Japan	APEC Center of Excellence Workshop: PMDA-ATC Medical Devices Workshop 2022 - Explanation of / Insight into the IMDRF Documents	Virtual	Nov. 14 - 16
SCU	China	2022 APEC Center of Excellence Training of the Review and Supervision of Implant Medical Devices	Virtual	Dec. 12 - 15

CoE Programs Planned for 2023

CoE	Economy	Planned Program	Format	Date
TFDA	Chinese Taipei	2023 APEC Medical Devices Regulatory Science CoE Workshop	In-Person & Virtual	Sept. 5 - 7
PMDA	Japan	APEC Center of Excellence Workshop: PMDA-ATC Medical Devices Workshop 2023	Virtual	Nov. 14-16
USC	United States	(CoE workshop)	In-person	Tentative (May)
SCH	Korea	(CoE workshop)	In-Person & Virtual	Tentative (Oct or Nov)
NEU	United States	(Pilot CoE workshop)	TBC	TBC

Next Steps

- Terms of Reference of APEC LSIF expired at the end of March 2022.
- RHSC is actively seeking a suitable home under APEC to continue regulatory convergence and cooperation efforts for medical products.
- A face-to-face meeting in Oakland, California, on 13-14 April 2023 will review the current work and strategize on the future of RHSC.
- Work is to be continued into 2023 in accordance with Vision 2030 and Strategic Framework.

IMDRF International Medical Device Regulators Forum

APEC Asia-Pacific Economic Cooperation

Thank you

IMDRF International Medical Device Regulators Forum | EU2023 EUROPEAN UNION Chair

16:10 – 16:25

Pan American Health Organization (PAHO)

Alexandre Lemgruber

Regional Advisor, Health Technologies, Pan American Health Organization (PAHO)

European Commission | European Union

IMDRF International Medical Device Regulators Forum

Update from the Pan American Health Organization

Alexandre Lemgruber

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			

IMDRF International Medical Device Regulators Forum

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!

Alexandre Lemgruber
lemgruba@paho.org

IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

16:25 – 16:40

The Global Diagnostic Imaging, Healthcare ICT, and Radiation Therapy Trade Association (DITTA)

Patrick Hope

Chair, The Global Diagnostic Imaging, Healthcare ICT, and Radiation Therapy Trade Association (DITTA)

European Commission | European Union

DITTA Report

IMDRF Open Stakeholder Forum

March 28, 2023

Patrick Hope, DITTA Chair

Executive Director, Medical Imaging and Technology Alliance

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

DITTA Global Presence

2018: DITTA recognized as a non state actor in official relations with WHO
2016: Signed MoU with the World Bank
2015: Granted NGO status with WHO
2014: Established official liaison with now-GHWP

DITTA: 11 WORKING GROUPS

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

1. Regulated Product Submission (RPS) Working Group — MITA
2. Cybersecurity Working Group — MITA
3. Medical Device Single Audit Program (MDSAP) Working Group — MITA
4. Unique Device Identification (UDI) Working Group — MITA
5. MSW & AI Working Group — COCIR
6. Clinical Evaluation Working Group — COCIR
7. Standardisation (STA) Working Group — COCIR
8. Good Regulatory Review Practices (GRRP) Working Group — JIRA
9. Global Health (GH) Working Group — COCIR
10. Environmental Policy (ENVI) Working Group — COCIR
11. Good Refurbishment Practice (GRP) Working Group — JIRA

IMDRF, GHWP, IEC, ISO

World Health Organization, World Bank Group, IAEA

Basel Convention, UNEP, IEC, ISO

COCIR, JIRA, Medtech Canada, MITA, THAIMED, IMEDA, 中国医疗器械行业协会 China Association for Medical Devices Industry, ABIMED, Kmdica, KMDIA Korea Medical Devices Industry Association, TECHNATION CA

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

Table of Contents

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

1. OUTCOMES OF IMDRF / DITTA/GMTA JOINT WORKSHOP ON POSTMARKET

(Attendees: 200+ registered)

Attendees: Patient, health care professionals, regulators, and industry

Themes:

- Safety notification and vigilance, including common terminology and templates;
- Identification and traceability of data (UDI)
- Risk-based differentiation for post-market
- Collection of data from users including health professionals
- Real-world evidence:
  - Build on existing guidances;
  - Enable access to data;
  - Advance stakeholder partnerships

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- Post-market for software:
  - Not different from traditional medical device post-market
  - Education and clarify on reportability criteria
  - Importance of interoperability
- Post-market for AI
  - Focus on training, clarity on intended use
  - Consideration of various sources and types of bias
- Conclusion: Working toward harmonization

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COCIR Advancing Healthcare · JIRA · Medtech Canada · MITA Medical Imaging & Technology Alliance · THAIMED · IMEDA · 中国医疗器械行业协 China Association for Medical Devices Ind. · ABIMED Associação Brasileira da Indústria de Tecnologia para Saúde · Kmdica Korea Medical Devices Industrial Coop. Association · KMDIA Korea Medical Devices Industry Association · TECHNATION CA

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

2. DITTA PRIORITY

- **Global harmonization and convergence of medical device regulations**

COCIR Advancing Healthcare · JIRA · Medtech Canada · MITA Medical Imaging & Technology Alliance · THAIMED · IMEDA · 中国医疗器械行业协 China Association for Medical Devices Ind. · ABIMED Associação Brasileira da Indústria de Tecnologia para Saúde · Kmdica Korea Medical Devices Industrial Coop. Association · KMDIA Korea Medical Devices Industry Association · TECHNATION CA

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

3. Feedback on IMDRF Work items

- Good Regulatory Review Practices (GRRP)
- Medical Device Cybersecurity Guide (CYBER)
- Artificial Intelligence Medical Devices (AIMD)
- Software as a Medical Device (SaMD)
- Standards
- Unique Device Identification Application Guide (UDI)
- Medical device single audit program (MDSAP)

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

3. Feedback on IMDRF Work items

1. Good Regulatory Review Practices (GRRP)

- DITTA welcomes the publication of the IMDRF N71 "Medical Device Review Report: Guidance regarding information to be included"
- DITTA supports further development of key elements for the CAB review system

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

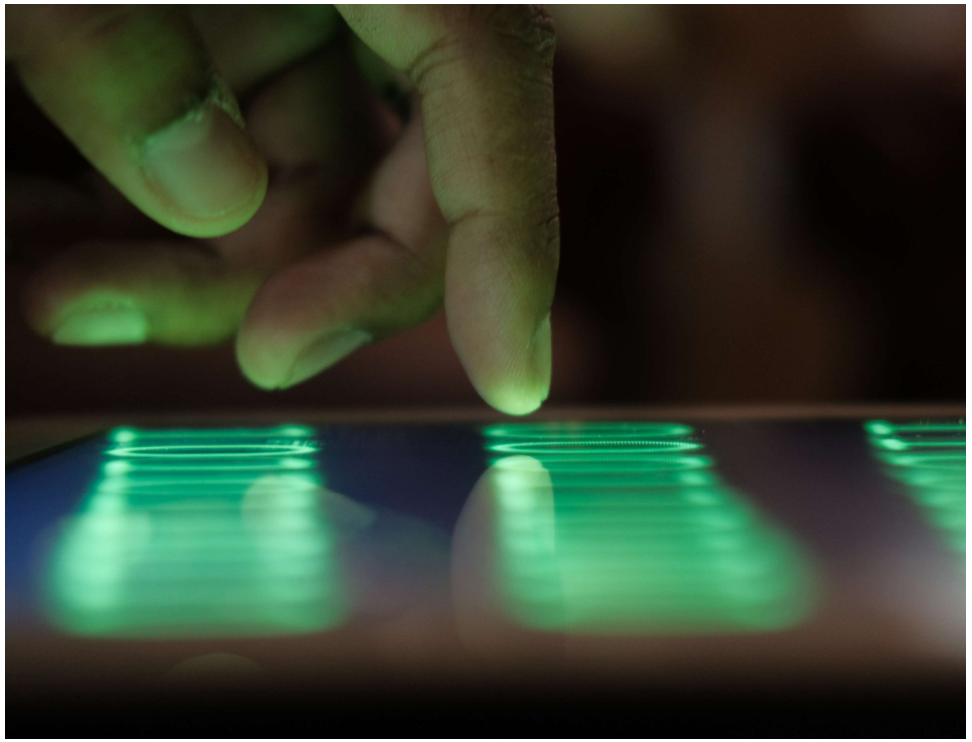
3. Feedback on IMDRF Work items

2. Medical Device Cybersecurity Guide (CYBER)

- DITTA is committed to working with the IMDRF to ensure that medical devices are deployed securely on networks and operate in a safe, effective way.

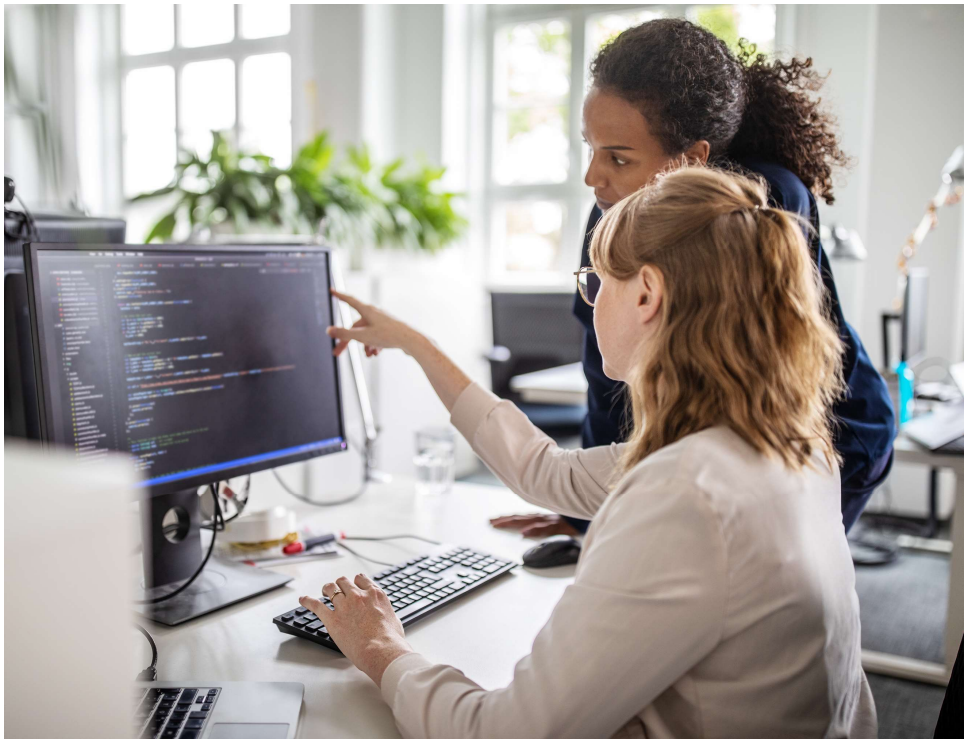
3. Artificial Intelligence Medical Devices (AIMD)

- DITTA supports the development of IMDRF guidance on Good Machine Learning Practice and Pre-Determined Change Control Plans.



DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

3. Feedback on IMDRF Work items



4. Software as a Medical Devices (SaMD)

- Support current activity to revise the existing SaMD documents.
- "SaMD Key Definitions (N10)" and on "Possible Framework for Risk Categorization and Corresponding Considerations (N12)"

5. Standards -Improving the quality of international medical device standards for regulatory use

- International standards are vital for global convergence
- Support "Standards Liaison Program Framework" (IMDRF/Standards WG/N72)
- IMDRF should actively use its liaison status at ISO and IEC to ensure regulators' input into development of standards for regulatory use is implemented.

COCIR Advancing Healthcare · JIRA · Medtech Canada · MITA Medical Imaging & Technology Alliance · THAIMED · IMEDA · 中国医疗器械行业协 China Association for Medical Devices Ind. · ABIMED Associação Brasileira da Indústria de Tecnologia para Saúde · Kmdica Korea Medical Devices Industrial Coop. Association · KMDIA Korea Medical Devices Industry Association · TECHNATION CA

3. Feedback on IMDRF Work items

6. Unique Device Identification Application Guide (UDI)

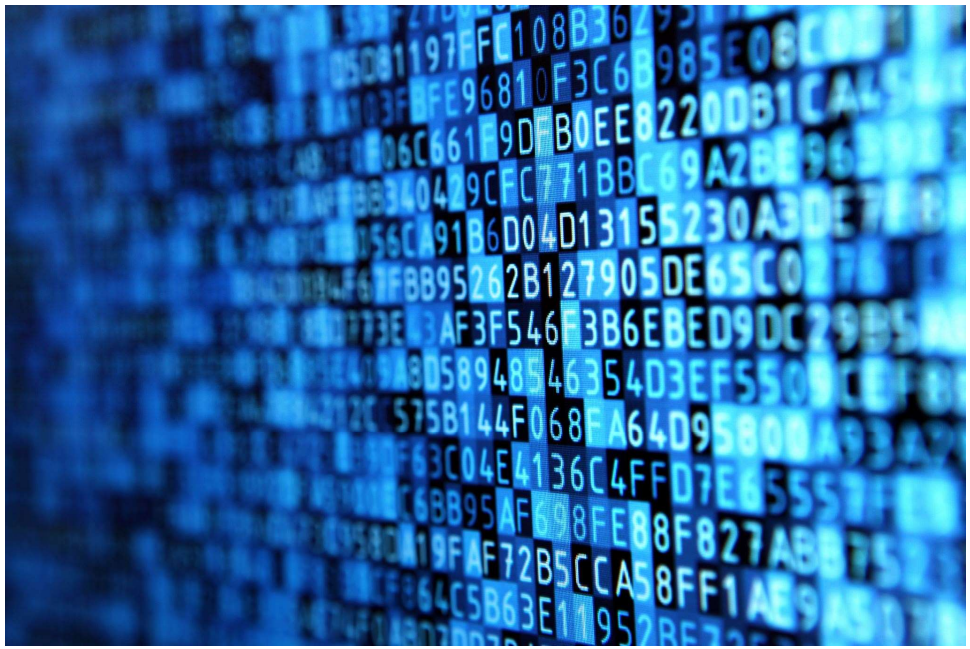
- Support global harmonization of UDI requirements
- Recommend updating documents:

"IMDRF/UDI WG/N53 "Use of UDI Data Elements across different IMDRF Jurisdictions"

"IMDRF/UDI WG/N48 "Application Guide"

7. Medical device single audit program (MDSAP)

- DITTA recommends that additional jurisdictions accept MDSAP reports in place of their need for audits
- DITTA encourages jurisdictions to become Members or Affiliates of the MDSAP Consortium



DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

THANK YOU!

www.globalditta.org

Follow us on @DITTA_online

IMDRF International Medical Device Regulators Forum | EU2023 EUROPEAN UNION Chair

16:40 – 16:55

Global Medical Technology Alliance (GMTA)

Diana Kanecka

Senior Manager International Affairs, MedtTech Europe

European Commission | European Union

Global Medical Technology Alliance

Innovating for a Healthier World

Reliance White Paper

IMDRF Stakeholders Session

March 28, 2023

Global Medical Technology Alliance
Innovating for a Healthier World

Presentation Outline

- Background
- Foundational Principles
- Core Tenets
- Next steps

Global Medical Technology Alliance
Innovating for a Healthier World

Background

- Regulators and manufacturers are committed to timely patient access to safe, effective, and quality medical devices

- Small differences in standards, guidance and regulations can cause major differences in the regulatory path (e.g., MD/IVD classification)

- These differences are amplified during a pandemic and seen in countless emergency use pathways

Global Medical Technology Alliance
Innovating for a Healthier World

Foundational Principles

- Implement convergent regulatory frameworks based on internationally recognized best practices and standards.
- Implement regulatory reliance, including recognition
- Implement core tenets of medical device regulations

284

Global Medical Technology Alliance
Innovating for a Healthier World

10 Core Tenets

- Ensure predictability and adequate resources
- Support innovation and apply equal regulation to both domestic and international companies
- Adopt Good Regulatory Practices (GRP)
- Avoid requirements that lack a patient safety benefit

Global Medical Technology Alliance
Innovating for a Healthier World

10 Core Tenets

- Accept global clinical trial data and leverage Real World Evidence
- Implement a risk-based approach to product changes
- Avoid unnecessary barriers to access based on product country of origin

Global Medical Technology Alliance
Innovating for a Healthier World

10 Core Tenets

- Implement a single dossier
- Adopt electronic instructions for use
- Accept digital labels

Global Medical Technology Alliance
Innovating for a Healthier World

Next Steps

- Disseminate and promote the principles of global convergence and regulatory reliance

- Cooperate with global regulators to get reliance in practice, not just on paper