

OUTCOME STATEMENT

**23rd Management Committee Meeting of the International Medical Device Regulators
Forum
27-31 March 2023
Brussels, Belgium**

The 23rd meeting of the International Medical Device Regulators Forum (IMDRF) Management Committee (MC) and Official Observers took place both in person in Brussels, Belgium, and online from 27 to 31 March 2023. The meeting was chaired by the EU. Around 300 participants attended in person and a further 200 virtual attendees participated in the first two public days. Presentations can be found [here](#).

Joint IMDRF / Stakeholder (DITTA-GMTA) Workshop

The life cycle of medical devices: the importance of post-market-related activities

On Monday 27 March 2023, the IMDRF/DITTA-GMTA Joint Workshop on ‘The life cycle of medical devices: the importance of post-market related activities’ was held. Regulators, industry representatives and healthcare professionals took part in four sessions and accompanying panel discussions with the first two sessions examining safety notices, vigilance and real-world evidence (RWE). Participants raised challenges and proposed ideas on how to improve current systems to ensure safe, performant and effective medical devices (MDs). They looked at possible ways to gather, validate and use RWE in the regulatory process and improve post-market surveillance. Sessions 3 and 4 dealt with post-market considerations for software, including artificial intelligence (AI) and for AI MDs. Attendees presented and discussed criteria, methods and strategies to monitor software safety and performance, including challenges and opportunities when collecting or generating data for digital MDs, as well as specific post-market considerations for AI MDs.

IMDRF Stakeholder Forum

On Tuesday 28 March 2023, the IMDRF Stakeholder Forum was held where regulatory updates were provided by IMDRF MC Members and Official Observers and representatives of eight of the IMDRF’s Working Groups, with a Q&A session following:

- Adverse Event Terminology – (USA/EU)
- Good Regulatory Review Practices – (USA/Singapore)

- Medical Device Cybersecurity Guide – (USA/Canada)
- Personalized Medical Devices – Australia
- Quality Management Systems – (USA/EU)
- Regulated Product Submission – (Canada/USA)
- Software as a Medical Device – (USA/Canada)
- Good Machine Learning Practice – (USA/UK)

Presentation materials were also provided to update on the work of:

- African Medical Devices Forum (AMDF)
- Asia-Pacific Economic Cooperation (APEC)
- Global Harmonization Working Party (GHWP)
- Pan American Health Organization (PAHO)
- Global Diagnostic Imaging, Healthcare ICT, and Radiation Therapy Trade Association (DITTA)
- Global Medical Technology Alliance (GMTA)

All presentation materials for the IMDRF/DITTA-GMTA workshop and the IMDRF Stakeholder Open Forum are available [here](#).

IMDRF Management Committee Open Session

On Wednesday 29 March 2023, the MC Open Session was held, providing an opportunity for Regional Harmonization Initiatives (RHIs), Invited Observers and the GMTA and DITTA to engage, provide updates and exchange views with the MC.

Presentations were made to update on the work of RHIs, including:

- African Medical Devices Forum (AMDF)
- Asia-Pacific Economic Cooperation (APEC)
- Global Harmonization Working Party (GHWP)
- Pan American Health Organization (PAHO)

Presentations were made to provide updates on the work of Invited Observers (Regulators):

- Israel Ministry of Health
- Saudi Federal Drug Agency
- South African Health Products Regulatory Authority (SAHPRA)
- Swiss Agency for Therapeutic Products (Swissmedic)
- Taiwan Food and Drug Administration (TFDA)

Presentations were made to provide updates on the work of industry associations:

- Global Diagnostic Imaging, Healthcare ICT, and Radiation Therapy Trade Association (DITTA)
- Global Medical Technology Alliance (GMTA)

IMDRF Management Committee Closed Session

The IMDRF MC Closed Session was held over two days, 30 and 31 March 2023. The MC discussed and took decisions regarding membership applications received, the documents presented by current Working Groups, as well as other procedural matters, including IMDRF governance documentation (See Annex).

ANNEX

DECISIONS BY THE IMDRF MANAGEMENT COMMITTEE

30 and 31 March 2023

Brussels, Belgium

In summary:

- The MC agreed to accept the application of Switzerland as an IMDRF Official Observer and South Africa as an IMDRF Affiliate Member.
- The MC agreed to postpone the decisions on other applications to June 2023.
- The MC agreed on a set of high-level strategic principles for IMDRF trainings. It was agreed to identify a pilot project and set up an MC sub-group for oversight on the trainings.
- The MC agreed to continue working on draft collaboration agreements between IMDRF and Regional Harmonisation Initiatives.
- The MC agreed to strengthen the existing legal disclaimers across IMDRF publications and platforms.
- The MC agreed that the public consultation for the following documents is extended by 45 days:
 - Non-In Vitro Diagnostic Device Regulatory Submission Table of Contents (nIVD ToC) (N9),
 - In Vitro Diagnostic Device Regulatory Submission Table of Contents (IVD ToC) (N13).
- The MC agreed that the following documents be published on the IMDRF website as Final Documents:
 - Principles and Practices for the Cybersecurity of Legacy Medical Devices (N70),
 - Principles and Practices for Software Bill of Materials for Medical Device Cybersecurity (N73),
 - Personalized Medical Devices – Regulatory Pathways (N58),
 - Personalized Medical Devices – Production Verification and Validation (N74),
 - Post Market Surveillance National Competent Authority Report Exchange Criteria and Report Form (N14) (Edition 4).
- The MC agreed to the publication of the IMDRF Strategic Plan 2021-2025 Progress Report Card in April 2023.
- The MC agreed to the publication of the White Paper produced by the Secretariat on the 23rd IMDRF Session Joint Workshop on the life cycle of medical devices: the importance of post-market related activities.
- The MC agreed to the rotation of the IMDRF secretariat and Chair to US FDA in 2024, followed by Japan in 2025. This will be published on the IMDRF website.