European Commission

Medical Device Coordination Group
14 October 2024

Agenda point 4 – International

Stakeholders session

14 October 2024

Agenda

a) MDSAP (formerly 4b)
b) IMDRF (formerly 4a)

- Debrief

- Strategic plan input

c) Reliance survey (additional point)

Debrief from MDSAP June 2024 Essen Germany

European Commission

2024 MDSAP Forum – Essen Germany

- The 2024 MDSAP annual Forum took place in Essen, Germany from **23-28 June 2024 in the premises of TUV Nord** – one of the designated notified bodies under Medical Device Regulation which is also an MDSAP Auditing Organisation.
- The Chair of the MDSAP RAC for 2024-2025 is Ms Tracey Duffy from Australia's Therapeutics Goods Administration.

Monday 24 June 2024 – participants: Regulatory Authorities and Official Observers

- ✓ The EU delegation informed in more detail the RAC members on the MDSAP information session that was organised on the 3 May 2024 to inform the Medical Device Coordination Group (MDCG) on the main aspects of the programme.
- ✓ The Chair provided a presentation on the activities related to the enhancement of MDSAP Performance.
- ✓ Of particular relevance to the EU are the activities related to: AO Acceptance Criteria**, Audit Report Quality Improvement**, and Non-Conformity Grading Improvement.

Tuesday 25 June 2024 – participants: Regulatory Authorities, Official Observers, Affiliates, Auditing Organisations and Industry partners

- ✓ Opening remarks were provided by the European Commission (Head of Unit of SANTE D3 – Medical Devices: Flora Giorgio).
- ✓ RAC members (US FDA, TGA Australia, ANVISA Brazil, Health Canada and PMDA Japan), Official Observers (WHO, EU, UK-MHRA, HSA Singapore) and Affiliates provided updates on their main regulatory developments.
- ✓ There were also different panel discussions where auditing organisations and industry partners discussed with regulatory authorities various aspects of the programme e.g MDSAP certificates, MDR-IVDR/MDSAP combined audits (largely used as AOs reported that around 60% of their MDR/IVDR audits are actually combined with MDSAP audits)

Wednesday 26 June 2024 AM- participants: Regulatory Authorities, Official Observers, Affiliates, Auditing Organisations and Industry partners

- The Commission participated in a panel discussion on ‘Observers Use of MDSAP’, flagging the importance that NBs, with the support of EU regulators, complete the mapping exercise (MDR-IVDR requirements vs MDSAP) to be used as a basis for any further engagement in the programme and showing interest in contributing with EU perspective to MDSAP enhancement priorities such us the audit report quality improvements and the non-conformity writing quality improvement.

Wednesday 26 June 2024 PM- participants: Regulatory Authorities, Official Observers, Auditing Organisations

- Notified bodies participating in the NBCG-Med task force on MDR-IVDR/MDSAP provided an update on their ongoing work on a gap analysis and mapping of the requirements under MDR/IVDR & MDSAP.
- Following finalisation of this work, the MDCG NBO group will have to assess their outcomes.
- As of 7 October 2024, the MDCG NBO leadership received the draft mapping work conducted by the task-force.

Thursday 27 & Friday 28 June 2024 - participants: Regulatory Authorities, Official Observers and MDSAP Auditing Organisations

- The last two days were dedicated to workshops and discussions on improvements needed to the program. The group was split into smaller groups who assessed real Audit Reports (the case studies) and answered a subset of questions related to:
- The quality of the Audit Report as well as their preference on the task-based or process-based approach.
- In addition, a discussion on remote and hybrid audits took place. Conflicting reports from AOs were noted (some indicating that MDSAP should follow the EU approach where others indicate difficulties in conducting combined audits because the EU approach was considered more restrictive).
- The final workshop was focused on the MDSAP AO assessment/recognition process. The EU was invited to provide a presentation on how the EU conducts its designation and notification process for notified bodies under the MDR and IVDR.

IMDRF

- Debrief

- Strategic plan input

European Commission

Debrief September 2024 – Seattle, Washington

Joint IMDRF/ Industry Workshop on Developing a Medical Device Regulatory System – 16/09

- The Joint IMDRF/Industry Workshop on Developing a Medical Device Regulatory System took place with speakers and panellists from regulatory authorities, industry, the World Health Organization (WHO), academia.

IMDRF Stakeholder Forum – 17/09

- The IMDRF Stakeholder Forum took place on 17 September 2024. Representatives from the IMDRF Management Committee (MC) and Official Observers (OO) briefed attendees on regulatory updates for their jurisdictions and answered questions.
- Representatives from the Good Regulatory Review Practices and the Clinical Evidence for IVDs Working Groups highlighted progress on their respective work items.
- Jurisdiction and regional updates from the following IMDRF Affiliate Members and Regional Harmonization Initiatives were also provided: EDA (Egypt), CInMED (Montenegro) and SAHPRA (South Africa), the Africa Medical Devices Forum (AMDF), Asia-Pacific Economic Cooperation (APEC), Global Harmonization Working Party (GHWP), and Pan American Health Organization (PAHO). Stakeholders provided In the final session of their perspective on what is challenging and what can be improved by the IMDRF in the new strategic plan.

Debrief September 2024 – Seattle, Washington

IMDRF Management Committee Open Session – 18/09

- The open session included the MC, OOs, RHIs, Affiliate Members, and invited observers seeking Affiliate and Official Observer membership.
- The IMDRF Secretariat highlighted the results of surveys undertaken by MC Members, OOs and Affiliate Members on reliance and electronic labelling. The session concluded with a moderated discussion of all attendees regarding how IMDRF can better engage with stakeholders on these topics.
- The afternoon of the open session featured a discussion about the Affiliate membership with the MC and OOs. Attendees explored the future of Affiliate membership, including benefits, challenges, and recommendations for how to better support and engage these members.

Debrief September 2024 – Seattle, Washington

IMDRF MC Closed Session – 19-20/09

- The MC agreed to accept the **applications for IMDRF Affiliate membership** submitted by: Botswana, Costa Rica, Dominican Republic, India, Oman, Paraguay, Peru, Zimbabwe.
- The MC agreed to accept the **application for IMDRF Official Observer** membership submitted by the Saudi Food and Drug Authority (SFDA) – Saudi Arabia.
- The MC agreed to:

  - ✓ Approve the final document titled “Common Data Set for Adverse Event Data Exchange Between IMDRF Regulators” (IMDRF AET WG/N85) from the Adverse Event Terminology (AET) Working Group.

  - ✓ Approve the draft document titled “Consideration for the selection of IMDRF Adverse Event Terminology codes and terms” for a 60-day public consultation.

  - ✓ Approved the revised New Work Item Proposal (NWIP) of the AI/ML Working Group for a document outlining a technical framework for AI lifecycle management and the SaMD WG NWIP on the essential principles and content of Predetermined Change Control Plans (PCCPs).

  - ✓ The MC agreed to collect feedback to inform the next IMDRF Strategic Plan (2026 – 2030).

- The MC confirmed that Japan will be the IMDRF Chair and Secretariat in 2025.

IMDRF 5-year strategic plan (2021-2025)

Mission of IMDRF
The mission1 of the International Medical Device Regulators Forum (IMDRF) is to strategically accelerate international medical device regulatory convergence to promote an efficient and effective regulatory model for medical devices that is responsive to emerging challenges in the sector while protecting and maximizing public health and safety.

IMDRF Key Objectives 2021-2025

1. *Managing regulatory challenges for medical devices and innovative technologies by providing timely and appropriate guidance*

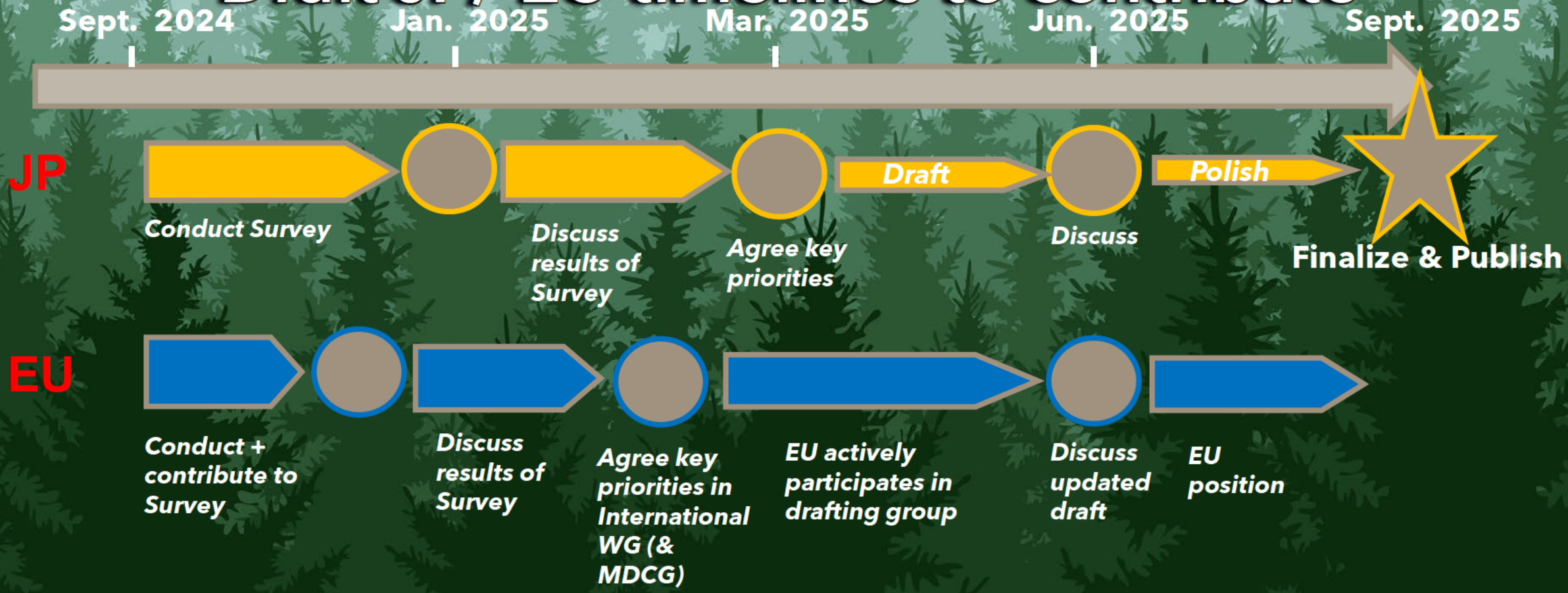
2. *Strengthening post-market surveillance for medical devices and implement regulatory lifecycle processes*

Priority 1: Pre-Market
- Topic: Personalized Medical Devices
- Topic: Software as a Medical Device
- Topic: Regulated Product Submissions
- Topic: Medical Device Evidence Evaluation (Clinical Evaluation)
- Topic: Good Regulatory Review Practice
- Topic: Artificial Intelligence Medical Devices

Priority 2: Post Market
- Topic: Cyber Security
- Topic: Adverse Event Terminology
- Topic: Unique Device Identifiers

Priority 3: Relationships with Stakeholders

IMDRF Strategic plan 202 2030
Draft JP/ EU timelines to contribute



SEATTLE WASHINGTON

FDA U.S. FOOD & DRUG ADMINISTRATION

IMDRF 2024 Chair

IMDRF International Medical Device Regulators Forum

Thank you

European Commission