



**OUTCOME STATEMENT  
of the IMDRF-20 Management Committee  
9 to 16 September 2021**

The twentieth meeting of the Management Committee (MC) of the International Medical Device Regulators Forum (IMDRF) took place over web conference from 9<sup>th</sup> to 16<sup>th</sup> September 2021. The meeting was chaired by the Republic of Korea. The MC consists of regulators from Australia, Brazil, Canada, China, the European Union (EU), Japan, Russia, Singapore, South Korea and the United States of America (USA). Representatives of the World Health Organization (WHO), the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom (UK) and the National Administration of Drugs, Food and Medical Devices (ANMAT) of Argentina\* participated as Official Observers.

#### **Joint Workshop**

On Thursday, September 9<sup>th</sup>, the IMDRF-DITTA Joint Virtual Workshop on Unique Device Identification (UDI) of medical devices was held. 770 stakeholders registered for the virtual workshop. Regulators provided background and introduction to the IMDRF UDI guidance documents and shared experiences in implementing their respective UDI systems. Industry representatives and a healthcare provider shared their experience and perspectives on the implementation and utilization of UDI in the supply chain. The panellists exchanged views on harmonization of the UDI data elements and requirements of the UDI regulations during the panel discussion following the presentations and Q&A sessions.

#### **Open MC Session**

On Monday, September 13<sup>th</sup>, the open session of the MC meeting was held to provide an opportunity for the global industry associations, Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA) and the Global Medical Technology Alliance (GMTA) to engage with the MC members and Official Observers. The Asia-Pacific Economic Cooperation Life Sciences Innovation Forum Regulatory Harmonization Steering Committee (APEC LSIF RHSC), the Asian Harmonization Working Party/Global Harmonization Working Party (AHWP/GHWP) and the Pan American Health Organization (PAHO) as Regional Harmonization Initiatives (RHIs) participated, and Swissmedic as an Invited Observer observed the meeting. GMDN Agency was invited to share recent updates on the GMDN nomenclature and to discuss global medical device nomenclatures. Discussions with the industry associations mostly focused on the IMDRF Work Items and future directions.

#### **Open Stakeholder Forum**

On Tuesday, September 14<sup>th</sup>, a Virtual Open Stakeholder Forum was held. 758 representatives from regulatory authorities, industry and the research community, etc. registered for the Forum. Due to time

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\* Argentina was accepted as Official Observer by the MC on 24 June 2021.

constraints of the webinar and to enable better interaction with stakeholders, some of the presentation materials were made available to participants beforehand for them to review and submit questions to be answered at the Forum. WHO, GMTA and South Korea shared lessons learned by responding to the pandemic during the special session.

The presentation materials were provided regulatory updates from each regulatory authority member country, Official Observers and each of IMDRF's eight current working groups.

The IMDRF's eight current working groups are:

- a. Regulated Product Submission – Canada/USA
- b. Good Regulatory Review Practice – Singapore/USA
- c. Medical Device Adverse Event Terminology – Japan
- d. Personalized Medical Devices – Australia
- e. Medical Device Clinical Evaluation – China
- f. Medical device Cybersecurity Guide – Canada/USA
- g. Principles of In Vitro Diagnostics (IVD) Medical Device Classification – Russia
- h. Artificial Intelligence Medical Devices – South Korea

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

1. World Health Organization (WHO)
2. APEC LSIF Regulatory Harmonization Steering Committee (RHSC)
3. Asian/Global Harmonization Working Party (AHWP/GHWP)
4. Pan American Health Organization (PAHO)
5. Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA)
6. Global Medical Technology Alliance (GMTA)

Presentations were delivered to share lessons learned, responding to COVID-19 from:

1. WHO
2. GMTA
3. South Korea

The Forum comprised of 4 segments where the panel addressed the questions received from participants:

1. Regulatory updates by IMDRF regulatory authority members
2. Progress of IMDRF work items
3. Stakeholders session
4. Special session: Lessons learned by responding to COVID-19

### **Closed MC Session**

At the closed session of the MC meeting on September 16<sup>th</sup>, the MC discussed and made decisions regarding the documents put forward from current working groups and some of the closed working groups, New Work Item Proposal proposed by an MC member, continuation of some of the working groups and other procedural matters (See Annex).

## ANNEX

### DECISIONS BY THE IMDRF MANAGEMENT COMMITTEE

In summary:

- The MC approved the Proposed Document, “Machine Learning-Enabled Medical Devices – A Subset of Artificial Intelligence-Enabled Medical Devices: Key Terms and Definitions”, of the Artificial Intelligence Medical Devices (AIMD) Working Group for a 60-day consultation period.
- The MC approved minor revisions on the IMDRF MDSAP documents, IMDRF/MDSAP WG/N4 “Competence and Training Requirements for Auditing Organizations”, “IMDRF/MDSAP WG/N6 “Regulatory Authority Assessor Competence and Training Requirements” and “IMDRF/MDSAP WG/N11 “MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization”.
- The MC decided in favor of closing the Medical Devices Clinical Evaluation (MDCE) and IVD Classification Working Group.
- The MC approved the NWIP: Review and Update of the GHTF clinical evidence documents for IVD medical devices, GHTF/SG5/N6 “Clinical Evidence for IVD Medical Devices – Key Definitions and Concepts”, GHTF/SG5/N7 “Clinical Evidence for IVD Medical Devices – Scientific Validity Determination and Performance Evaluation” and GHTF/SG5/N8 “Clinical Evidence for IVD Medical Devices – Clinical Performance Studies for IVDs”, proposed by Russia.
- The MC continued the discussions on the implementation table and agreed to keep updating the table.
- The MC agreed that a brief statement on responding to pandemics will be on the IMDRF website.