IMDRF International Medical Device Regulators Forum

IMDRF Jurisdictions Harmonization Efforts and WGs updates

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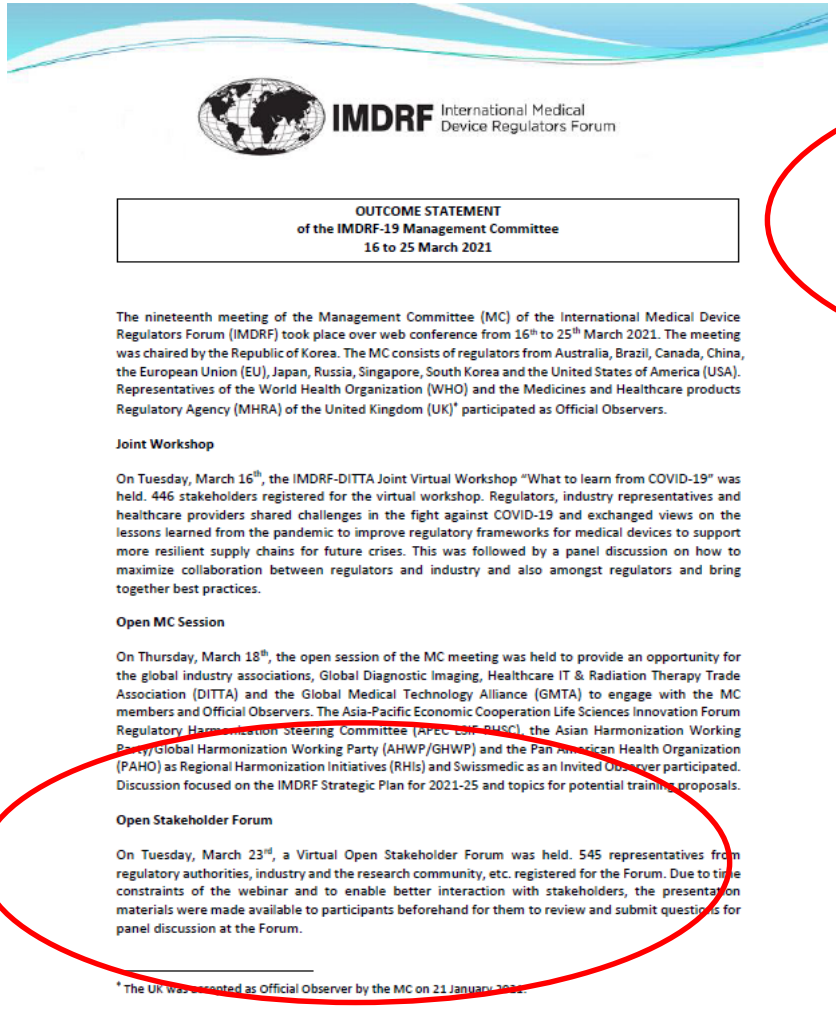
IMDRF's Efforts for Regulatory Harmonization (2021)



IMDRF International Medical Device Regulators Forum

OUTCOME STATEMENT
of the IMDRF-19 Management Committee
16 to 25 March 2021

The nineteenth meeting of the Management Committee (MC) of the International Medical Device Regulators Forum (IMDRF) took place over web conference from 16th to 25th March 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) and the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom (UK)* participated as Official Observers.

Joint Workshop

On Tuesday, March 16th, the IMDRF-DITTA Joint Virtual Workshop "What to learn from COVID-19" was held. 446 stakeholders registered for the virtual workshop. Regulators, industry representatives and healthcare providers shared challenges in the fight against COVID-19 and exchanged views on the lessons learned from the pandemic to improve regulatory frameworks for medical devices to support more resilient supply chains for future crises. This was followed by a panel discussion on how to maximize collaboration between regulators and industry and also amongst regulators and bring together best practices.

Open MC Session

On Thursday, March 18th, 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) and Swissmedic as an Invited Observer participated. Discussion focused on the IMDRF Strategic Plan for 2021-25 and topics for potential training proposals.

Open Stakeholder Forum

On Tuesday, March 23rd, a Virtual Open Stakeholder Forum was held. 545 representatives from regulatory authorities, industry and the research community, etc. registered for the Forum. Due to time constraints of the webinar and to enable better interaction with stakeholders, the presentation materials were made available to participants beforehand for them to review and submit questions for panel discussion at the Forum.

* The UK was accepted as Official Observer by the MC on 21 January 2021.

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The presentation materials provided regulatory updates from each MC 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
b. Good Regulatory Review Practice – USA/Singapore
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)
7. Korea Medical Devices Industry Association (KMDIA)
8. Korea Medical Devices Industrial Cooperative Association (KMDICA)
9. American Society for Testing and Materials (ASTM) International

The Forum comprised 3 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

Closed MC Session

At the closed session of the MC meeting on March 25th, the MC discussed and made decisions regarding the documents put forward from current working groups, New Work Item Extensions proposed by MC members, IMDRF SOP and other procedural matters (See Annex).

IMDRF's Efforts for Regulatory Harmonization (2021)

Australia's progress

Fully implemented

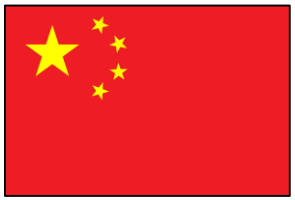
- ✓ Medical Device Single Audit Program
- ✓ Medical device cybersecurity
- ✓ National Competent Authorities Reports Exchange Program
- ✓ Edition 4.1 of adverse event terminology

Partially implemented or still in progress

- Common principles on registries
- Development of Regulatory Product Submissions
- Good Review Practices for pre-market reviews
- Improving medical device standards (via Standards Australia)
- Improving quantity and quality of clinical data
- Software as a Medical Device
- Personalised medical devices
- Rules for unique device identifiers

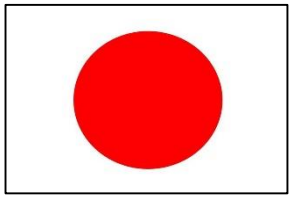
- Cybersecurity
- SaMD
- UDI

- UDI



- Fully implemented : 14 guidelines
- Partly implemented: 14 guidelines

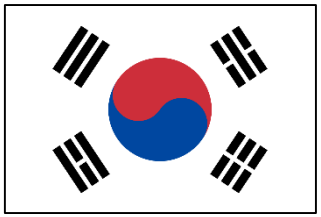
UDI



- SaMD

- SaMD

- UDI
- SaMD



- SaMD

- AI/ML based SaMD

Working Group	Current Activities	Milestone
Regulated Product Submission (HC & US FDA)	**NWIE** "Evolution of the In Vitro Diagnostics and Non-In Vitro Diagnostics Device Market Authorization Table of Contents documents (IMDRF/RPS WG/N9 and IMDRF/RPS WG/N13) "	-
Good Regulatory Review Practice (US FDA & HSA)	**NWIE** Development of a reporting model for medical device regulatory reviews conducted by conformity assessment bodies (CABs)	**Draft for Public Consultation** March, 2022

Working Group	Current Activities	Milestone
Adverse Event Terminology (MHLW & PMDA)	**NWIE** Signal Detection Maintenance	**IMDRF Terminology Revision (Maintenance)** March, 2022
Personalized Medical Device (TGA)	**NWIE** PMD Production Validation -Part I : Validation aspects of a specified design envelope -Part II : Validation aspects of an Medical Device Production System	**Draft for Public Consultation** March, 2022 **Final Document** September, 2022

Working Group	Current Activities	Milestone
Medical Device Clinical Evaluations (NMPA)	**Closed**	
Medical Device Cybersecurity Guide (US FDA & HC)	**NWIE** Medical Device Cybersecurity Deeper Dive: Legacy Devices and Transparency of Software Components Including Use of Third-Party Software	**Draft for Public Consultation** April, 2022 **Final Document** March, 2023

Working Group	Current Activities	Milestone
Principles of In Vitro Diagnostic (IVD) Medical Devices Classification (Roszdravnadzor)	**Closed**	
Artificial Intelligence Medical Devices	**NWIP** Machine Learning-enabled Medical Devices—A subset of Artificial Intelligence-enabled Medical Devices: Key Terms and Definitions(Draft) (60 days Public Consultation)	**Final Document** March, 2023

Working Group	Current Activities	Milestone
Review and Update of the GHTF clinical evidence documents for IVD medical devices (Roszdravnadzor)	**NWIP** 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	-

Thank you