IMDRF 2023

24th session

25-26 September 2023 | Berlin, Germany

The IMDRF Management Committee (MC) welcomed 350+ professionals to Berlin who participated to the EU chaired sessions as follows:

Day 1 - 25 September 2023

Joint IMDRF / Stakeholder (DITTA-GMTA) Workshop - Specialized Regulatory Pathways

Opening remarks

- **Andrzej Rys**, Chair EU2023, IMDRF
- **Annabel Seebohm**, Vice-Chair, Global Diagnostic imaging, healthcare IT & radiation Therapy Trade Association (DITTA)
- **Jesus Rueda Rodriguez**, Co-Chair, Global Medical Technology Alliance (GMTA)

Overview of IMDRF foundational pathways

- **Donal O'Connor**, Clinical Manager, Health Products Regulatory Authority (HPRA)
- **Greg Le Blanc**, Director, Regulatory Affairs and Quality Systems, Cook Medical, Canada

Devices intended for specific patient populations

Orphan and humanitarian-use medical devices

- **Donal O'Connor**, Clinical Manager, Health Products Regulatory Authority (HPRA)

- **Tetsuya Kusakabe**, Director of Office of Manufacturing Quality and Vigilance for Medical Devices, International Coordination Officer Pharmaceuticals and Medical Devices Agency (PMDA)
- **Leo Hovestadt**, EU Director Governmental Affairs, Elekta
- **Cho Ahram**, Deputy Director, Ministry of Food and Drug Safety (MFDS), South Korea
- **April Veoukas**, Director Regulatory Affairs, Abbott

Paediatric medical devices

- **Kenneth Cavanaugh**, Deputy Office Director, U.S Food and Drugs Administration (FDA)
  Joel Batts, Senior Vice President of Clinical & Regulatory Affairs, OrthoPaediatrics
- **Berthold Koletzko**, Professor of Paediatrics, LMU University Hospitals

Devices intended for specific patient populations

Personalized and custom medical devices

- **Tracey Duffy**, First Assistant Secretary, Medical Devices and Product Quality Division, TGA
- **Mariana Madureira**, Senior Officer, Health Products Directorate, INFARMED
- **Jan Demol**, Regulatory Affairs Manager, Materialise
- **Matthias Neumann**, Deputy Head Medical Devices Safety Unit, German Federal Ministry of Health
- **Christophe Carrein**, Director Quality & Compliance, Velsera

Devices intended for specific patient populations

Panel discussion – lessons learned and opportunities for improvement

Moderators**: Janet Trunzo**, Chair, Global Medical Technology Alliance (GMTA)
& **Matthias Neumann**, European Commission

- **Donal O'Connor**, Clinical Manager, Health Products Regulatory Authority (HPRA)
- **Tetsuya Kusakabe**, Director of Office of Manufacturing Quality and Vigilance for Medical Devices, International Coordination Officer Pharmaceuticals and Medical Devices Agency (PMDA)
- **Kenneth Cavanaugh**, Deputy Office Director, U.S Food and Drugs Administration (FDA)

- **Leo Hovestadt**, EU Director Governmental Affairs, Elekta
- **Joel Batts,** Senior Vice President of Clinical & Regulatory Affairs, OrthoPaediatrics
- **Tracey Duffy**, First Assistant Secretary, Medical Devices and Product Quality Division, TGA
- **Jan Demol**, Regulatory Affairs Manager, Materialise

Innovative medical devices

Existing pathways for innovative medical devices

- **Erin Cutts**, Senior International Policy Analyst, FDA
- **Sally Prawdzik**, Acting Director, Policy and International Programs, Health Canada
- **Woei Jiuang Wong**, Assistant Group Director of Medical Devices Cluster, Health Products Regulation Group, Health Sciences Authority (HSA)
- **Joao Martins**, Associate Director Regulatory Affairs Strategy, Abbott
- **Yujin Lee**, Chief Medical Officer, WELT Corp
- **Nataliya Deych**, Vice President Regulatory Affairs (EMEACLA), Edwards Lifesciences
- **Helmut Scherer**, Chief Technology Officer, Erbe Elektromedizin

Opportunities for convergence and reliance

- **Augusto Bencke Geye**r, General Manager, General Management of Health Product Technology, ANVISA
- **Yasha Huang**, Head of Regulatory Policy Asia Pacific, Roche Diagnostics
- **Johanna Sorsa**, Senior Manager Clinical and Regulatory Affairs, Siemens Healthineers
- **Latifa Lakehal**, Head of Standards and Regulations, Philips
- **Diane Wurzburger**, Executive Regulatory Affairs & Quality, Developed Markets & Global Strategic Policy, GE Healthcare

Innovative medical devices

Panel discussion – lessons learned and opportunities for improvement

Moderators: **Diane Wurzburger**, GE Healthcare & **Steffen Buchholz**, DE – EU

- **Sally Prawdzik**, Acting Director, Policy and International Programs, Health Canada
- **Erin Cutts**, Senior International Policy Analyst, FDA
- **Joao Martins**, Associate Director Regulatory Affairs Strategy, Abbott
- **Yujin Lee**, Chief Medical Officer, WELT Corp

- **Augusto Bencke Geyer**, General Manager, General Management of Health Product Technology, ANVISA
- **Johanna Sorsa**, Senior Manager Clinical and Regulatory Affairs, Siemens Healthineers

Regulatory toolboxes to foster innovation

Regulatory sandboxes

- **Paul Campbell**, Innovative Devices at the Medicines and Healthcare products Regulatory Agency (MHRA)
- **Nada Alkhayat**, Policy Officer, Directorate General for Health and Food Safety, European Commission
- **Koen Cobbaert**, Senior Manager - Quality, Standards & Regulations, Philips
- **Bettina Möbius**, Director Regulatory Affairs, Dräger

Predetermined change controls and innovative tools in the regulatory toolbox

- **Yuang Peng**, Division Director, Department of Medical Device Registration, National Medical Products Administration (NMPA)
- **Russell Pearson**, AI Regulation and Policy Specialist, Innovative Devices at the Medicines and Healthcare products Regulatory Agency (MHRA)
- **Cassie Scherer**, Senior Director, Digital Health Policy & Regulatory Strategy, Medtronic
- **April Veoukas**, Director Regulatory Affairs, Abbott
- **Anna Hallersten**, Head Regulatory Policy Europe, Roche Diagnostics

Regulatory toolboxes to foster innovation

Panel discussion – lessons learned and opportunities for improvement

Moderators: **Jesus Rueda**, Global Medical Technology Alliance (GMTA) & **Rolf Oberlin Hansen**, International Representative, Danish Medicines Agency

- **Russell Pearson**, AI Regulation and Policy Specialist, Innovative Devices at the Medicines and Healthcare products Regulatory Agency (MHRA)
- **Koen Cobbaert**, Senior Manager - Quality, Standards & Regulations, Philips
- **Yuang Peng**, Division Director, Department of Medical Device Registration, National Medical Products Administration (NMPA)
- **Paul Campbell**, Innovative Devices at the Medicines and Healthcare Products Regulatory Agency (MHRA)
- **Cassie Scherer**, Senior Director, Digital Health Policy & Regulatory Strategy, Medtronic
- **Anna Hallersten**, Head Regulatory Policy Europe, Roche Diagnostics

Closing remarks

- **Andrzej Rys**, Chair EU2023, IMDRF

Day 2 - 26 September 2023

IMDRF Stakeholder Forum

Opening remarks

- **Andrzej Rys**, Chair EU2023, IMDRF
- **Edgar Franke**, Parliamentary State Secretary to the Federal Minister of Health, Germany

Regulatory updates from IMDRF Management Committee and Official Observers including short updates from IMDRF Working Groups

- Australia - **Tracey Duffy**, First Assistant Secretary, Medical Devices and Product Quality Division, TGA
- Brazil - **Augusto Bencke Geyer**, General Manager, General Management of Health Product Technology, ANVISA
- Canada - **Sally Prawdzik**, Acting Director, Policy and International Programs, Health Canada
- China - **Yuan Peng**, Division Director, Department of Medical Device Registration, NMPA
- European Union - **Nada Alkhayat**, Policy Officer, Directorate General for Health and Food Safety, European Commission & **Chloe Spathari**, Policy Officer, Directorate General for Health and Food Safety, European Commission

Regulatory updates from IMDRF Management Committee and Official Observers including short updates from IMDRF Working Groups

- Japan - **Tomoyuki Miyasaka**, Deputy Director, Medical Devices Evaluation Division, MHLW

- Singapore - **Wong Woei Jiuang**, Assistant Group Director, Medical Devices Cluster, HSA
- South Korea - **Jeong-Rim Lee**, Director General, Medical Device Evaluation Department, MFDS
- United Kingdom - **Laura Squire**, Chief Healthcare Quality and Access Office, Medicines and Healthcare products Regulatory Agency (MHRA)
- United States of America - **Kenneth Cavanaugh,** Deputy Director, Office of Cardiovascular Devices, US FDA

Official observers:

- Argentina - **Yesica Anastasio**, Coordinator of the International Relations Program, National Administration of Drugs, Food and Medical Devices (ANMAT)
- Switzerland - **Markus Wälti**, Head of Division, Swiss Agency for Therapeutic Products (Swissmedic)
- World Health Organization (WHO) - **Hiiti Baran Sillo**, Unit Head, Regulation and Safety Department of Regulation and Prequalification

Stakeholders sessions

- African Medical Devices Forum (AMDF) - **Paulyne Wairimu**, Chair
- Asia Pacific Economic Cooperation (APEC) - **Cheng-Ning (Emily) Wu**, Senior Technical Specialist, Division of Medical Devices and Cosmetics, Taiwan Food and Drug Administration
- Global Harmonization Working Party (GHWP) - **Bryan So**, Executive Secretary General
- The Global Diagnostic Imaging, Healthcare ICT, and Radiation Therapy Trade Association (DITTA) - **Patrick Hope**, Chair
- Global Medical Technology Alliance (GMTA) - **Diana Kanecka**, Senior Manager International Affairs, MedTech Europe

Flash panel - exchange of experience and best practices

Unique Device Identification – 10 years down the road

Moderator: **Orla Daly**, Policy Officer, Directorate General for Health and Food Safety, European Commission

- **Erin Cutts**, Senior International Policy Analyst, U.S. Food and Drug Administration
- **Silvia Ostuni**, Legal and Policy Officer, European Commission
- **Tang Jinglong**, NMPA
- **Dennis Black**, UDI Programme Director, BD

- **Tania Pearson**, Regulatory Systems Director, Medtronic
- **Tracey Duffy**, First Assistant Secretary of the Medical Devices and Product Quality Division, Therapeutic Goods Administration, Australia

‘Digital Therapeutics’ – Let’s talk qualification and clinical evidence

Moderator: **Nada Alkhayat**, Policy Officer, Directorate General for Health and Food Safety, European Commission

- **Lee Chung-Keun**, Ministry of Food and Drug Safety (MFDS), South Korea
- **Rolf Oberlin Hansen**, International Representative, Danish Medicines Agency
- **Paul Campbell**, Innovative Devices, Medicines and Healthcare Products Regulatory Agency (MHRA)
- **Lim Jin Hwan**, AIMMED
- **Tobias Schreiegg**, Director Regulatory Affairs, Siemens Healthineers
- **Ittipan Kanluan**, Regulatory Affairs Manager, Roche Diagnostics
- **Koen Cobbaert**, Senior Manager - Quality, Standards & Regulations, Philips

Closing remarks

- **Andrzej Rys**, Chair EU2023, IMDRF

Information session: EU Medical Devices Regulation – extension of the transition period explained

The aim of this information session is to explain the EU Medical Devices Regulation (MDR) amendment adopted in March 2023 (Regulation (EU) 2023/607) and discuss its practical implementation from different angles.