CORE-MD

Coordinating Research and Evidence for Medical Devices

Regulatory science for high-risk medical devices: CORE–MD and beyond

Final Conference

De Warande Club, Brussels (and online)

15th March 2024

Conference objectives:

- ◊ To review the current state of implementation of the EU Medical Device Directives
- ◊ To present the results of the EU Horizon H2020 CORE–MD project (2021–2024)
- ◊ To consider how clinical experts should contribute to the EU regulatory system
- ◊ To consider what developments and reforms are needed.

09:00 – 10:00	***Registration***
10:10 – 11:00	**Welcome**
Introduction to the CORE–MD Coordination & Support Action	**Alan Fraser**, CORE-MD Scientific Coordinator, *European Society of Cardiology*
10:10 – 11:00	**Session 1: Reflections on the European regulatory system for medical devices**
Per Kjærsgaard-Andersen, Chair EU Affairs Committee, *European Federation of National Associations of Orthopaedics and Traumatology (Chair)* **Rainer Becker,** Director, *European Commission, Directorate-General for Health and Food Safety, Medical Products and Innovation (SANTE.D)* **Contribution from** *Belgian Presidency of EU / Ministry of Health* **Peter Liese**, MEP, IVDR Rapporteur, *European Parliament*	
11:00 – 11:30	***Coffee break***
11:30 – 13:00	**Session 2: Main outcomes of the Horizon 2020 CORE–MD project**
Paul Piscoi, Scientific Policy Officer, *European Commission, DG SANTE, Medical Devices (SANTE.D.3) (Co-Chair)* **Anne Lübbeke-Wolff**, Associate Professor, Division of Orthopaedics and Trauma Surgery, *Geneva University Hospitals (Co-Chair)*	
Clinical evaluation and transparency of evidence	**Robert Byrne**, Chair of Cardiovascular Research, *Royal College of Surgeons of Ireland*
Improving the quality of post-market surveillance	**Perla Marang-van de Mheen**, Associate Professor, *Delft University of Technology*
Regulation of AI medical devices	**Frank Rademakers**, Emeritus Professor, *Katholieke Universiteit Leuven*
Providing medical devices for children	Berthold Koletzko, President, *European Academy of Paediatrics*
Panel discussion	

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 965246

13:00 – 14:00	***Lunch***
14:00 – 15:15	**Session 3: Science-based regulatory policy for medical devices**
Rob Nelissen, Secretary General, *European Federation of National Associations of Orthopaedics and Traumatology (Co-Chair)* **Rita Redberg**, Professor of clinical medicine, *University of California, San Francisco (Co-Chair)*	
Recommendations from the CORE–MD consortium	**Alan Fraser**, CORE-MD Scientific Coordinator, *European Society of Cardiology*
Regulatory science at the European Medicines Agency	**Miguel Antunes**, Senior Scientific Officer, *Expert Panels and Groups, European Medicines Agency*
The perspective of patients	**Penilla Gunther**, President, *European Patient Safety Foundation*
Public responsibilities of the notified bodies	**Sabina Hoekstra**, Vice President, *European Association Notified Bodies for MDs and IVDs*
Panel discussion	
15:15 – 15:30	**Coffee break**
15:30 – 16:30	**Session 4: Global regulatory convergence – priorities for development**
Niall McAleenan, Director of Medical Devices, *Health Products Regulatory Authority Ireland (Co-Chair)* **Elizabeth Macintyre**, President, *Biomedical Alliance in Europe (Co-Chair)*	
Review by the European Commission	Flora Giorgio, Head of Unit, *European Commission, DG SANTE, Medical Devices (SANTE.D.3)*
The role of the World Health Organization	**Adriana Velazquez Berumen**, Group Lead Medical Devices and In-Vitro Diagnostics, *World Health Organization*
The view of European manufacturers	**Petra Zoellner**, Director Regulatory Affairs (IVDR & MDR), *MedTech Europe*
Comments from the FDA and IMDRF	**Kenneth Cavanaugh**, Deputy Director, *Office of Health Technology, Cardiovascular Devices, U.S. Food and Drug Administration*
Panel discussion	
Summary and conclusion	

All times are CET.

Participation in person is available at no cost on a first-come first-served basis. Live webcasting will be also available. **Pre-registration is required for both in person and online participants at this link.**

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