COCIR SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

COCIR
EU REGULATORY AFFAIRS ANNUAL DAY 2019

MEDICAL DEVICE REGULATION

WEDNESDAY **10 APRIL 2019** COCIR OFFICES, BRUSSELS

BENEFITS OF ATTENDING THIS SEMINAR:

- Gain insight into the latest developments in the MDR implementation process
- Develop your network with industry experts, regulators, Notified Bodies and other stakeholders active in MDR
- Understand what you still need to do to prepare
- Use the opportunity to ask specific questions about clinical evaluation, PMS & Vigilance, transitional provisions or other topics

PRICE

250€ PP
60€ PP (SME)
FREE FOR COCIR MEMBERS, REGULATORS, NOTIFIED BODIES & NOT-FOR-PROFIT ORGANISATIONS

REGISTER HERE

WHO SHOULD ATTEND

This event is primarily intended for manufacturers of medical devices, including SMEs, who are in the process of preparing for and implementing the Medical Device Regulation. Other stakeholders such as regulators, notified bodies and non-profit organisations could also be interested.

DRAFT PROGRAMME

The Date of Application of the Medical Device Regulation is little more than a year away. It is thus the right time to take stock of the implementation progress and ask ourselves: are we ready? This event will dive into the main priority topics in the implementation process and offer an excellent opportunity for discussion between regulators, industry and other stakeholders. The insights provided cover a broad range of subjects, from the pre-market obligations, post-market surveillance and vigilance, including related changes in the obligations for all economic operators, to a dedicated exchange on the transitional provisions and how we can ensure that they are feasible and sustainable for industry and regulators. This year will be the first time that our COCIR Annual EU Regulatory Affairs Days are opened to an audience beyond the COCIR membership.

10:00	WELCOME COFFEE
10:30	**WELCOME** & **INTRODUCTION**
10:35	KEY NOTE: **MEDICAL DEVICES AND THE EUROPEAN SINGLE MARKET**
10:50	SESSION 1 **MEDICAL DEVICE REGULATION AND PRE-MARKET OBLIGATIONS** We will address the progress in implementing pre-market obligations, focussing on requirements in the area of clinical evaluation and investigation. Multi-stakeholder panellists will also discuss challenges arising for economic operators in the pre-market phase, especially verification activities and UDI requirements
12:00	SESSION 2 **MEDICAL DEVICE REGULATION AND HARMONISED STANDARDS** Harmonised Standards are an essential element supporting the new Regulation. Based on the draft standardisation request that is expected to be published in the first or second quarter of this year, panellists actively involved in standardisation activities will discuss the next steps towards the adoption of the request and the practical work to be done in the standardisation organisations. In addition, this session will address broader challenges for the harmonisation of standards for medical devices.

13:00	LUNCH BREAK
14:00	UPDATE ON **EUDAMED** IMPLEMENTATION
14:20	SESSION 3 **MEDICAL DEVICE REGULATION AND POST-MARKET OBLIGATIONS** Interpretation of the post-market surveillance obligations and reports for economic operators, including manufacturers, distributors and importers, is on-going, with many guidance documents and templates still under development. An holistic overview of all PMS mechanisms and required reports will be presented, including the MIR Form, Adverse Event reporting and timelines, Feld Safety Corrective Action (FSCA) and the Vigilance module in EUDAMED will be discussed.
15:20	COFFEE BREAK
15:40	SESSION 4 **MEDICAL DEVICE REGULATION AND TRANSITIONAL PROVISIONS** With the Date of Application coming very close, understanding the transitional provisions, the so-called “grace period” becomes crucial. This panel will discuss how industry can make best use of the grace period and what exactly the obligations for legacy devices are, as well as the broader implications of this critical period between the Directives and Regulation for industry, Regulators and Notified Bodies.
16:50	**CONCLUDING REMARKS**
17:00	RECEPTION & NETWORKING

REGISTRATION

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