Bocconi

ISSUE PANEL – INDEPENDENT SCIENTIFIC OPINION FOR CE MARK OR EARLY DIALOGUE FOR HTA: A UNIQUE EXPERT PANEL FOR BOTH?

ISPOR EUROPE 2021

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12.30-13.30 CET

Università Bocconi
CERGAS
Centre for Research on Health and Social Care Management

SDA Bocconi
School of Management

Acknowledgments

The moderator and the presenters of this Issue Panel declare they have no conflict of interests.

Mr Andrea Rappagliosi works at Edwards Life Science.

Background

- The European Union (EU) Medical Devices Regulation 2017/745 (**MDR**) became effective in May 2021 with a **key aim to improve clinical evidence generation**
- The legislative proposal for regulation of health technology assessment (HTA) in the EU is expected by the end of 2021 and should **support market access processes for innovative technologies by centralizing clinical assessments**
  - These regulations foresee **a key role for expert panels** to inform Notified Bodies (NBs) during conformity assessment for CE mark and in early dialogue for HTA for coverage decisions
  - Previous experience in the pharma sector shows that strict collaboration between the regulatory and HTA processes (i.e., joint assessments by EMA and EUnetHTA) can benefit the industry and the entire ecosystem
  - But **how and whether expert panels in the regulatory and HTA processes of medtech should be combined remains an open question**

Aims

The panel will:

- debate the benefits and intended/unintended consequences of instituting a unique expert panel for CE mark and HTA.
- address how a unique panel might negatively/positively affect timely, equal access to safe, effective innovation, and
- how such a proposal might affect the roles of NBs and various stakeholders, including European and national regulatory agencies, HTA bodies, payers, policymakers, manufacturers, patients.

Panelists	Perspective
Paul Piscoi, MD, Scientific Policy Officer, Medical Devices, European Commission, Brussels, Belgium	The EU scientific policy perspective regarding EU cooperation on HTA, the proposed EU HTA Regulation and MDR, and the role of expert panel(s)
Sabina L. Hoekstra-van den Bosch, PharmD, FRAPS, Regulatory Strategy Principal, TÜV SÜD Medical Health Services, Veenendaal, Netherlands	Notified Body perspective on interaction with EU and HTA bodies, stakeholders and manufacturers, and whether and how a unique CE Mark/HTA expert panel might fit in the current scenario.
Andrea Rappagliosi, MSc, Vice President, Market Access and Public Affairs, Edwards Life Science, Nyon, VD, Switzerland	The Medical Device industry perspective on pathways to CE Mark and reimbursement under MDR and proposed EU HTA Regulation, addressing interactions with Notified Bodies and stakeholders and clinical documentation
Rosanna Tarricone, PhD, Associate Dean, SDA Bocconi School of Management, Bocconi University, Milan, IT	Moderator

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What might be a disadvantage of having a unique Expert Panel for CE Mark and HTA?

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What might be a benefit of having a unique Expert Panel for CE Mark and HTA?

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THANK YOU.

ROSANNA.TARRICONE@UNIBOCCONI.IT

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