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THE EVOLVING EU POLICY LANDSCAPES: ARE WE ON THE RIGHT PATH TO IMPROVE CLINICAL AND ECONOMIC OUTCOMES RESEARCH OF MEDICAL DEVICES?

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Premise

- With the increasing demand by patients and clinicians to timely access novel therapies, funding bodies are asked to take decisions on coverage & reimbursement shortly after, or even in parallel, to their regulatory approval
- At the early stage of the technology's life cycle, the evidence-base to support funding decisions is rather limited and is focused on the regulatory bodies' expectations, i.e. [efficacy and] safety vs. comparative effectiveness & cost-effectiveness, i.e. what the reimbursement authorities do expect to appraise

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Premise 2

- At this stage the level of uncertainty is high and making funding recommendations is risky since it may lead to suboptimal decisions:
  - A technology may receive a positive recommendation but then it shows to be less safe and effective than expected which may impact health outcomes and allocation of scarce resources
  - Access to the technology may be delayed till new evidence emerges but this may lead to forgo relevant health benefits if the technology reveals to be as promising as expected

Introduction to the Issue Panel

- Clinical evidence for medical devices is often deemed to be poor in quantity and quality (RCTs):
  - Current regulatory systems mainly aim at assessing safety & performance and not efficacy & effectiveness
  - Medical devices' features (e.g. learning curve, incremental innovation) make clinical evidence generation more challenging than drugs

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Introduction to the Issue Panel 2

Better clinical evidence for high risk and implantable medical devices based upon technologies characteristics and previous consultation of experts

Is the evolving EU landscape aimed at improving clinical and economic evidence of medical devices so to reconcile different stakeholders' expectations?

Better functioning of the internal market & health protection through Joint Clinical Assessments [and Joint Scientific Advice]

REGULATIONS

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 5 April 2017
on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
(Text with EEA relevance)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on health technology assessment and amending Directive 2011/24/EU

(Text with EEA relevance)
{SWD(2018) 41 final} - {SWD(2018) 42 final}

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Introduction to panelists

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ANDREA RAPPAGLIOSI
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